ACCU-CHEK®

Smart Pix

SOFTWARE

User's Manual

Roche

Accu-Chek® Smart Pix software User's Manual

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System requirements:

- Microsoft Windows XP / Vista, Windows 7 / Windows 8 (in compatibility mode)
- PDF reader
- Screen resolution of at least 1024 x 768 pixels

Please read the User's Manual carefully before the first use. The installation, use and maintenance/data backup of the Accu-Chek Smart Pix software are the sole responsibility of the user. Roche Diagnostics accepts no responsibility for any damage or loss resulting from non-compliance with this User's Manual.

In addition, we advise you to refrain from installing any software on your computer which is not from a trustworthy source and to protect your computer against unauthorised third-party access. This particularly applies to the security of any existing Internet access. Please use up-to-date software for virus protection and your firewall and install the security updates and patches recommended by the manufacturers.

The USB flash drive is the original medium used to provide the software, but it is not a removable medium for storing data you have created yourself. Avoid potential data loss (e.g., from damage to or loss of the USB flash drive) and always store all files locally on your computer or on a network server.

Do not remove the USB flash drive containing the Accu-Chek Smart Pix software while data is being exchanged. Doing so could cause irreparable damage to files.

Important note: The displayed blood glucose *Status* will only be meaningful if the settings have been properly selected. We therefore strongly recommend that you talk to your healthcare team before you change the configuration for Hypo risk, Mean blood glucose and Variability.

The number of tests per test day must be sufficient in order to draw appropriate conclusions regarding therapy from the statistical analysis. In addition, the tests must be conducted at meaningful points in time spread over the course of the day. Only then does the analysis in the *Status* report element correctly reflect the relevant blood glucose parameter. If, for example, blood glucose is only tested when blood glucose levels are within the normal range (euglycaemia) or higher range (hyperglycaemia), the *Hypo risk* is artificially lowered.

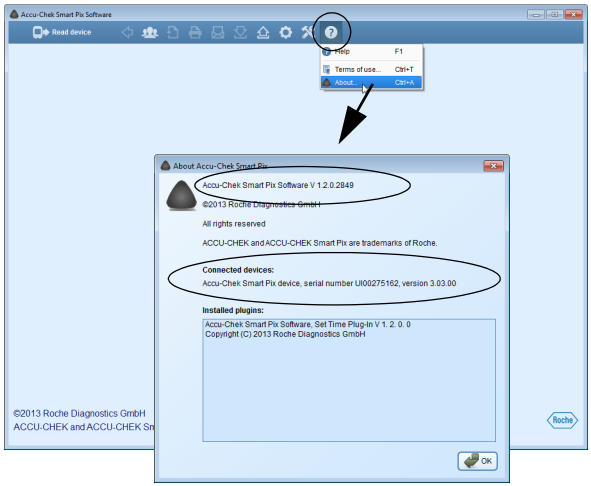
Important note: The *Hypo limit* can only be a reliable indicator of hypoglycaemia (low blood glucose) if the limit has been properly selected. We therefore strongly recommend that you talk to your healthcare professional or healthcare team before you change the limit. This function is not a substitute for hypoglycaemia training by your healthcare professional or healthcare team.

Important note: Never make changes to your therapy plan based on data contained in the *Status* report element; always talk to your healthcare team first.

Version note

This User's Manual is valid for the

- Accu-Chek Smart Pix software, **version 1.2**, in connection with an
- Accu-Chek Smart Pix device reader, **version 3.04** or higher.


Accu-Chek Smart Pix Software
Read device
Help F1
Terms of use... Ctrl+T
About... Ctrl+A
About Accu-Chek Smart Pix
Accu-Chek Smart Pix Software V 1.2.0.2849
©2013 Roche Diagnostics GmbH
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Connected devices:
Accu-Chek Smart Pix device, serial number UI00275162, version 3.03.00
Installed plugins:
Accu-Chek Smart Pix Software, Set Time Plug-In V 1. 2. 0. 0
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OK
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You can check the software versions at any time as described below:

Open the Help menu by clicking the icon (on the right-hand edge of the button bar). You can display the software version by clicking *About…* This displays both the software version of the Accu-Chek Smart Pix software and the version of the connected Accu-Chek Smart Pix device reader.

Latest software versions
You can download the latest software version of the Accu-Chek Smart Pix system using the relevant *Tools* button or as an automatic download (if configured) from the Internet.

You do **not** require an Internet connection if you wish to use the Accu-Chek Smart Pix device reader and the Accu-Chek Smart Pix software. All the pages and functions are stored in the device itself or in the software, where they can be called up. An Internet connection is only required if you wish to download the Accu-Chek Smart Pix software from the Internet or send data by email.

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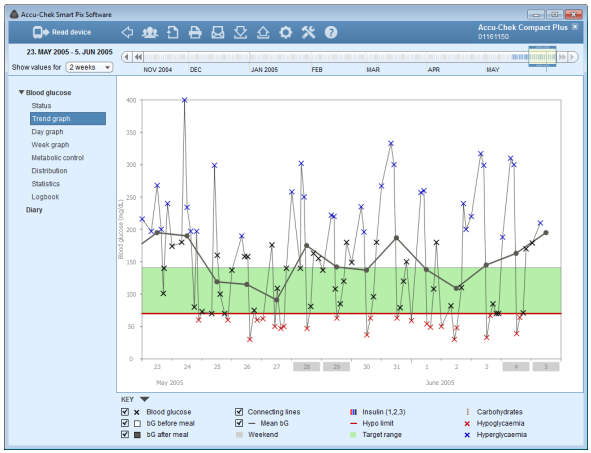
1 Accu-Chek Smart Pix software overview

The **Accu-Chek Smart Pix device reader** is used to easily and automatically analyse blood glucose values and therapy data from various Accu-Chek meters and insulin pumps. The analysis is provided on a computer in the form of a report consisting of various configurable report elements. The system is made up of the following components:

- Accu-Chek Smart Pix device reader. It is connected to the computer and will usually assume the task of communicating with meters and insulin pumps which have an infrared port.
- Accu-Chek Smart Pix software. This software generates reports and allows managing the records of several users or patients.

Using the system is very intuitive:

- Connect the Accu-Chek Smart Pix device reader to the computer when you want to read data from a meter or an insulin pump with an infrared port, **or**:
- Use a USB cable to connect a meter with its own USB port directly to the computer.
- Launch the Accu-Chek Smart Pix software.



The **Accu-Chek Smart Pix software** is a computer program for the Accu-Chek Smart Pix system. It contains the following functions:

- Create (and edit) reports.
- Archive reports with selected elements as a PDF file.
- Email reports with selected elements.
- Display and print archived reports.
- Manage and edit user or patient records.
- Importing device data as well as printing and saving reports can be automated.
- The graphical report elements displayed have interactive functions for customising the display.
- Install software updates for the Accu-Chek Smart Pix system.

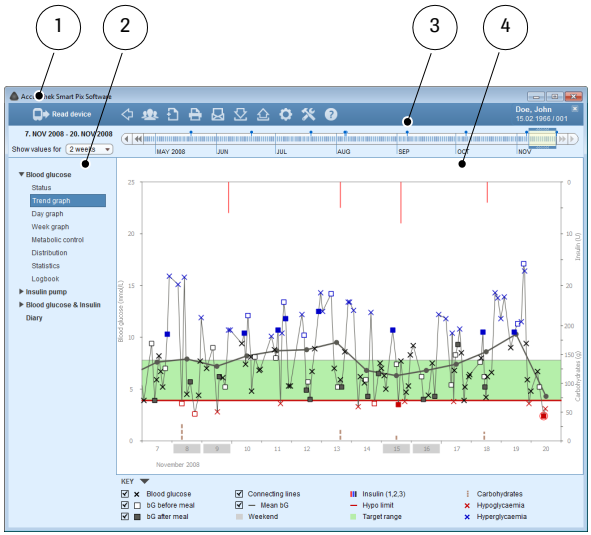
All reports displayed and the use of all functions take place completely within the Accu-Chek Smart Pix software.

1.1 Printed symbols

Some passages in this User's Manual are highlighted by symbols. Please read these passages very carefully! There are more symbols on the type plate of the device and/or the packaging.

Symbol	Description
	This symbol draws your attention to important information.
	Manufacturer
	Catalogue number
	Batch code - year of manufacture
	The Accu-Chek Smart Pix software fulfils the requirements of the European Directive 93/42/EEC on medical devices. The USB flash drive fulfils the requirements of the European Directive 2004/108/EC on electromagnetic compatibility.
	This product fulfils the legal requirements of the People's Republic of China on the use of certain substances in electronic products.
	The USB flash drive falls inside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment, WEEE).
	Consult instructions for use. The Accu-Chek Smart Pix software User's Manual can be found on the supplied USB flash drive.
	A printed version of the Accu-Chek Smart Pix software User's Manual can be requested by emailing dia.smartpix@roche.com.

1.2 Accu-Chek Smart Pix software overview



The Accu-Chek Smart Pix software consists of the following elements:

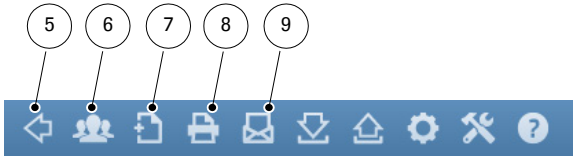
1	Title bar of the program window, showing the program name and the buttons for minimising, maximising and closing the window.
2	Navigation area
3	Button bar containing the buttons for calling up program functions.
4	Display pane for showing the reports and records.

The user interface needs a screen resolution of at least 1024 x 768 pixels. On larger screens, the window size can be changed in any way inside the screen area.

Note about the illustrations in this User's Manual

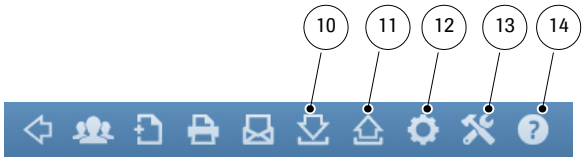
Please bear in mind that all the illustrations of screen content used in this User's Manual (screenshots) only serve as examples in terms of visual appearance and content. The actual appearance depends on your individual system and program settings. The displayed contents depend on the meter data or insulin pump data that was read.

1.3 Buttons overview



In the program window you will find the following buttons:

5	*Back* button Returns to the report element that was displayed last. This button is only activated once you leave the displayed start screen to display another report element.
6	*Open diary* button You can open an existing record from the patient list or create a new record.
7	*Save* button A record that was just displayed but not yet assigned to a patient can then be saved.
8	*Print* button Selected report elements are output to a printer of your choice.
9	*Email* button The default email program on the computer is launched and selected report elements are automatically attached to an empty email (as a PDF file).



10	*Save as PDF report* button Selected report elements are saved in a PDF file.
11	*Open PDF report* button Open reports previously saved as PDF files in order to display them using the PDF reader installed on the computer (e.g., Adobe Reader), or to print them.*
12	*Settings* button Use this button to adjust the settings for the Accu-Chek Smart Pix software.
13	*Tools* button Access to special functions such as software updates.
14	*Help* button Open the program's Help system or display the program version.

* If you do not yet have a program for displaying PDF files on your computer, you can download, e.g., Adobe Reader from the Adobe website (http://get.adobe.com/reader/) free of charge.

2 Prior to using the Accu-Chek Smart Pix software

You can use the Accu-Chek Smart Pix software on any computer which meets the necessary requirements for the Accu-Chek Smart Pix device reader. Any additional computer features required are listed below.

The Accu-Chek Smart Pix software is supplied on a USB flash drive or can be downloaded from the Internet. When using the USB flash drive, you can easily copy the program files stored on the flash drive to a computer (see page 17). The software can be used on a standalone computer as well as on a network server.

Files generated (e.g., records, archived reports) are either saved locally or on a server, where they are available for shared access. Just as with all other data you should protect these files from inadvertent data loss by backing them up regularly.

The USB flash drive is the original media used to provide the software but it is not a removable media for storing data you have created yourself. Avoid potential data loss (e.g., from damages to or loss of the USB flash drive) and always store all files locally on your computer or on a network server.

2.1 What you require for using the Accu-Chek Smart Pix software

Required items:

- The Accu-Chek Smart Pix device if you wish to read data from meters or insulin pumps with their own infrared ports, and/or:
- A suitable USB cable (USB, micro B to USB, type A), if you wish to read data from meters with a USB port.
- A computer that meets the respective system requirements and a printer, if you wish to print reports.
- Adobe Reader or a similar program must be installed to be able to display and print PDF files.

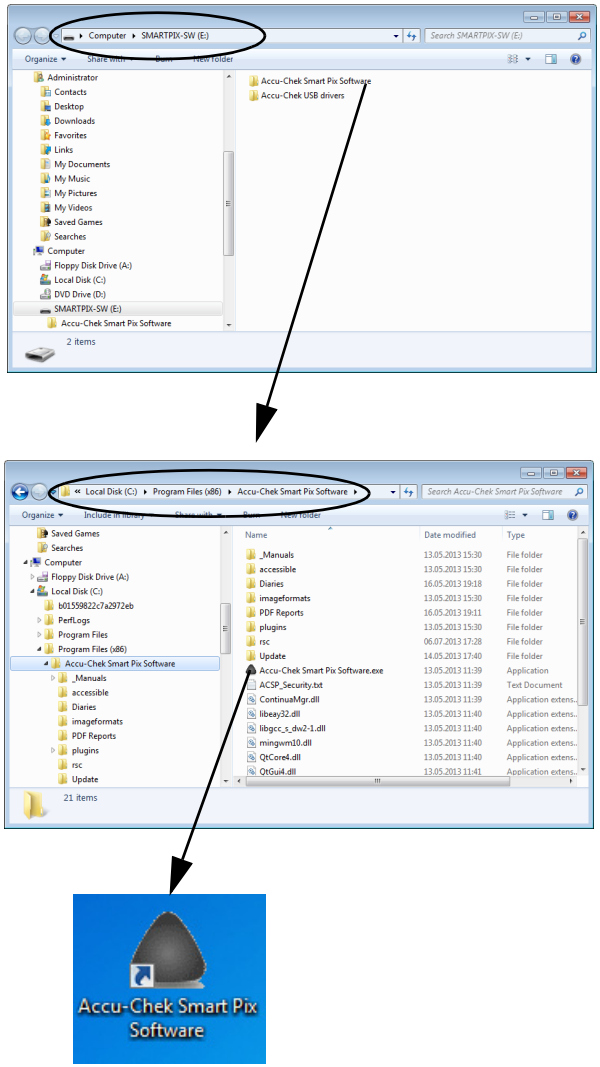
The following requirements must be met to be able to use special functions:

- An additional free USB port if you wish to use not only the Accu-Chek Smart Pix system but also further Accu-Chek devices with their own USB interface.
- Internet access to download software updates and to send emails.
- A properly configured email program (Microsoft Outlook, Windows Live Mail or Mozilla Thunderbird) to be able to email reports.

2.2 Copying software to the computer

The Accu-Chek Smart Pix software can be used locally on your computer or on a network server. To do this, copy the program files to a suitable location on the selected hard disk. Depending on your needs, you have the following options:

- If you are the only person who will be using the program, copy the program locally to your computer. You will also save the created files there.
- If you want to use the program in a network and if the same program settings are to apply for every workstation, then copy the program files to the network server. You will also save the created files there. On the server, the program can also be launched by several network users at the same time.
- If you want to use the program in a network, but allow individual program settings for every workstation, copy the program separately to every single workstation. The created files, however, will be saved on the server to enable shared access of all data despite individual settings.



Proceed as follows:

- Open a window on your computer displaying the contents of your hard disk (your boot drive, usually C:). You can do this from *My Computer* or Windows Explorer.
- Open the desired target folder into which you wish to copy the “Accu-Chek Smart Pix software” folder.
  - If you always work using administrator access rights, open the *Programs* folder (or *Programs (x86), if applicable).*
  - If you do not always work using administrator access rights, select a folder which can be accessed, even with limited access rights, e.g. *Documents*.
  - When installing the program on a network server, ensure that all users have the necessary access rights for the selected folder.
- Copy the complete “Accu-Chek Smart Pix software” folder from the USB flash drive to the selected folder.
- You may create a shortcut to the *Accu-Chek Smart Pix software.exe* program file for launching it conveniently from the Start menu or from the desktop. You will find detailed information on this under the keyword “Shortcut” in the Windows Help system.

If you are using the application on several computers in the network, make sure that the location for saving the shared files is identical on every computer.

2.3 Connecting the Accu-Chek Smart Pix device and/or USB cable

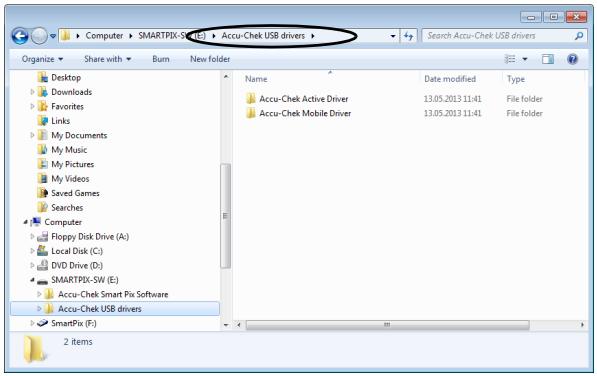
Connecting the Accu-Chek Smart Pix device

Insert the USB plug of the Accu-Chek Smart Pix device to a free USB port on your computer. You can do this while your computer is either on or off. This connection provides the Accu-Chek Smart Pix device with power and it therefore does not need a battery or a power pack.

After connecting the Accu-Chek Smart Pix device and, as the case may be, turning on the computer, the central luminous surface as well as the left and right lights light up. Simultaneously, the computer recognizes the Accu-Chek Smart Pix device as a removable media (similar to a USB flash drive). The luminous surface then begins to flash. Different light signals indicate various operating statuses. After connecting the Accu-Chek Smart Pix device or after turning on the computer, the following display indicates fully-functional operation.

- The top/bottom dots flash slowly (approximately once per second).

This display indicates operational readiness and active searching for meters and/or pumps. The Accu-Chek Smart Pix system is now ready to read data from these devices.



Installing USB drivers

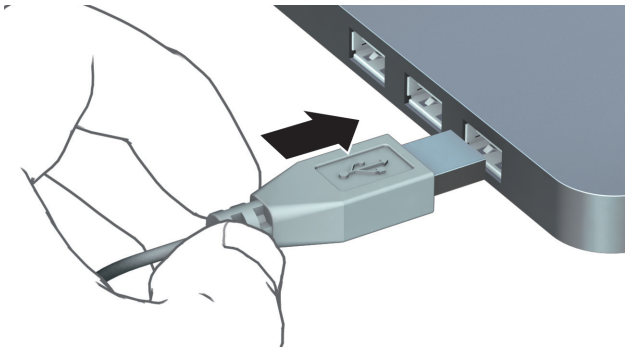
If you want to read data from a meter with a USB port, the corresponding *PHDC Continua* driver must be installed before you connect the meter. You will find the installation programs required in the *Accu-Chek USB drivers* folder.

Open the folder with the same name as the desired meter and then the folder *...Driver* (for 32-bit operating systems) or *...Driver X64* (for 64-bit operating systems). Start the installation program contained in the folder (*dpinst.exe* or *dpinst64.exe*) and follow the instructions on the screen.

Administrator access rights are required for installing the USB driver software.

Once the installation finishes, the computer can communicate with the selected meter.

Connecting the USB cable

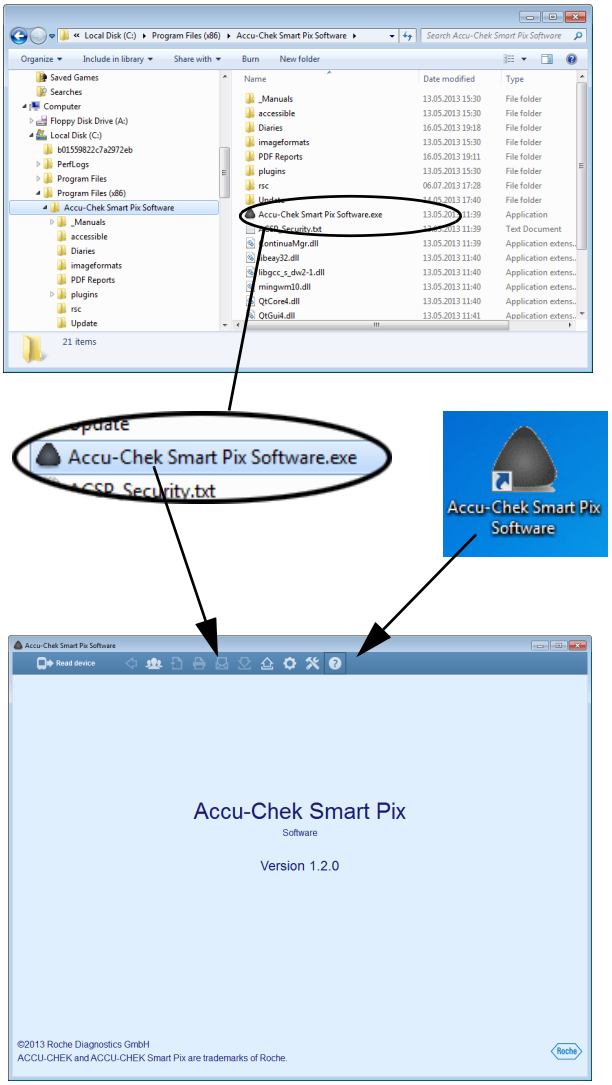


For meters with a built-in USB port, you will need a suitable USB cable (USB type A to the computer and micro USB type B to the meter). In order to transfer data, connect the cable to the meter first and then to the computer.

Insert the USB plug of the cable to a free USB port on your computer. You can do this while your computer is either on or off.

3 Launching and configuring the Accu-Chek Smart Pix software

3.1 Launching the Accu-Chek Smart Pix software



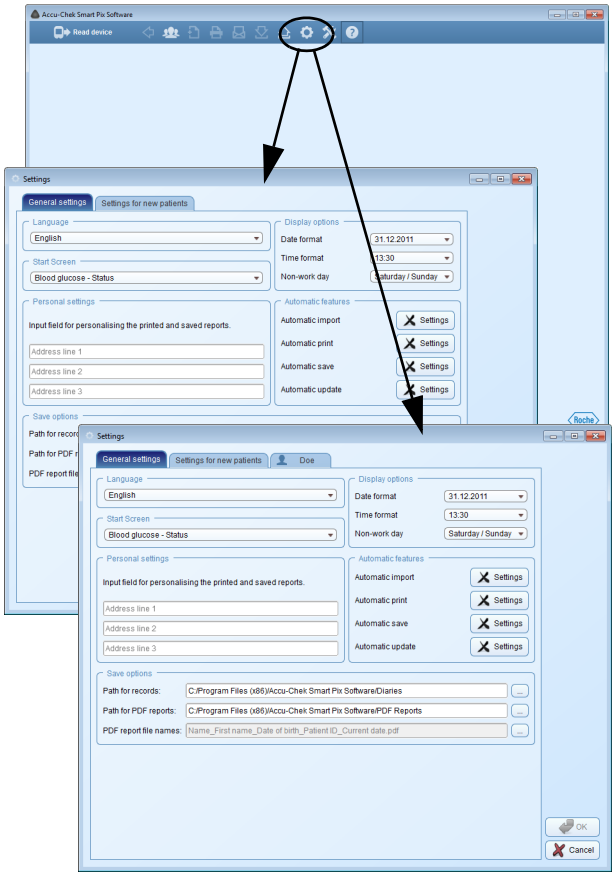
In order to launch the Accu-Chek Smart Pix software, double-click either the program file *Accu-Chek Smart Pix software.exe* or the link you have created (see chapter 2.2).

The program launches with a program window which is still empty.

- If you only wish to use the program to edit a record already saved or to display saved reports it is not necessary to connect the Accu-Chek Smart Pix device reader.
- If you wish to use the program to read new data, connect the Accu-Chek Smart Pix device reader or a suitable meter (e.g., the Accu-Chek Mobile blood glucose meter directly via USB) now.

If a suitable device is already connected, you can use the *Read device* button to read the data directly from the device.

3.2 Configuring the Accu-Chek Smart Pix software



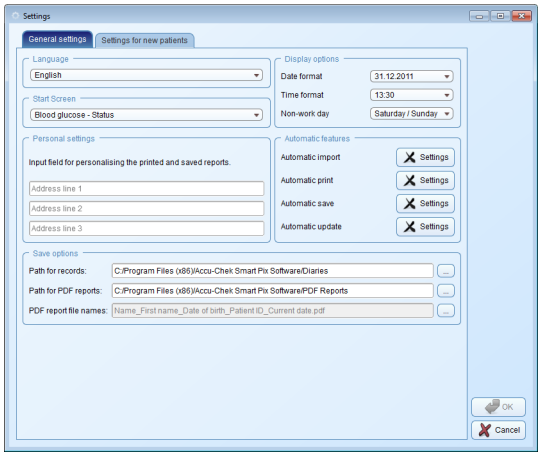
You can customise several areas of the Accu-Chek Smart Pix software to tailor it to your needs. These settings are independent of those applied to the Accu-Chek Smart Pix device.

Click the *Settings* button to open the corresponding dialog box. Depending on the actual situation you will find two or three setup areas in this dialog box. This can be seen from the tabs below the upper window edge:

- If no record is currently open, you will find **two** setup areas, *General settings* and *Settings for new patients*.
- If a record is open, you will find **three** setup areas. In addition to the ones mentioned above, you will find a third area whose name corresponds to the open record.

For all the settings described on the following pages, the following applies:

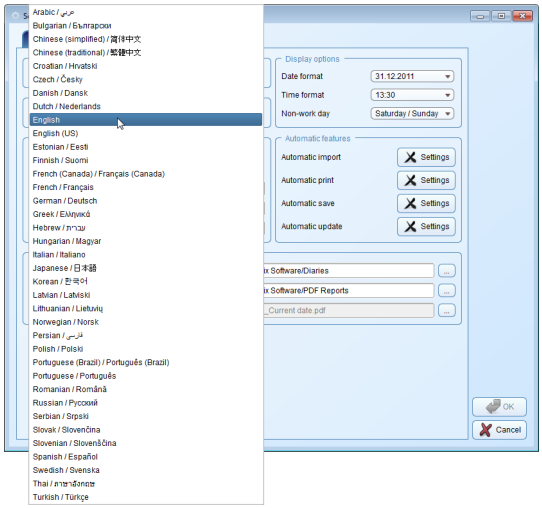
- Click the *OK* button to save the modified settings and to close the dialog box, or:
- Click the *Cancel* button to discard the modified settings and to close the dialog box without saving the changes.



General settings

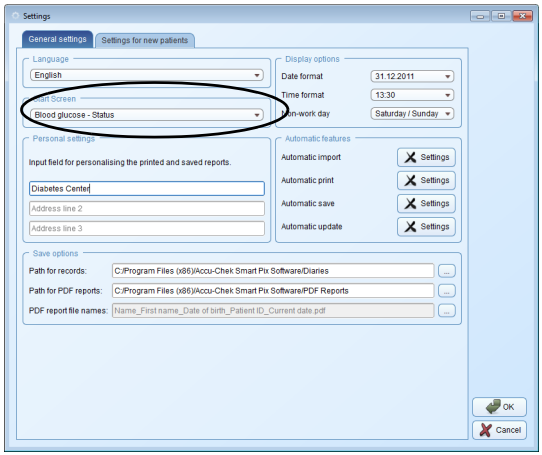
In the *General settings* area you will find configuration options for the user interface.

- *Language:* Here you can select the language to be used for the user interface and the reports. If the Accu-Chek Smart Pix software supports the language set in the device reader, the language will be set automatically.
- *Start screen:* Select the start screen you wish to use for the reports. This screen will be displayed automatically after reading device data. You can select any of the available report elements for this screen.
- *Personal settings:* Input fields for personalising printouts or saved files.
- *Display options:* Here you can set the date and time format and the non-work days for displaying reports.
- *Automatic features:* Here you can set automatic program functions supporting the use of the system in a doctor's practice or another medical institution. You can configure device data to be automatically read, saved or printed. Updates for the Accu-Chek Smart Pix system can also be downloaded automatically from the Internet.
- *Save options:* Here you can select the location for saving patient data (records), as well as naming conventions and the location for saving PDF reports.



Selecting a language

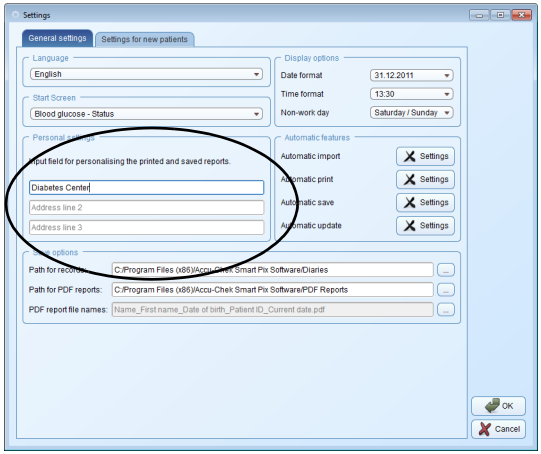
- Click the currently set language to open the selection list.
- Click the language you want to select.



Start screen

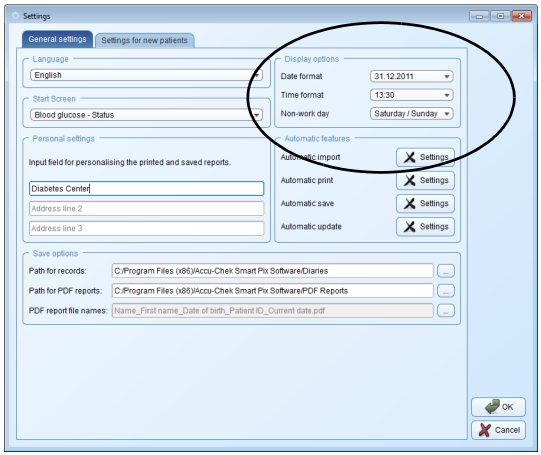
- Select the report element to display as the start screen.

If the report element selected here is not available in the currently displayed report, (e.g., the *Status* report element after reading from an insulin pump), another start screen will be displayed as an alternative: *Status* for blood glucose meters, and *Trend graph* for insulin pumps.



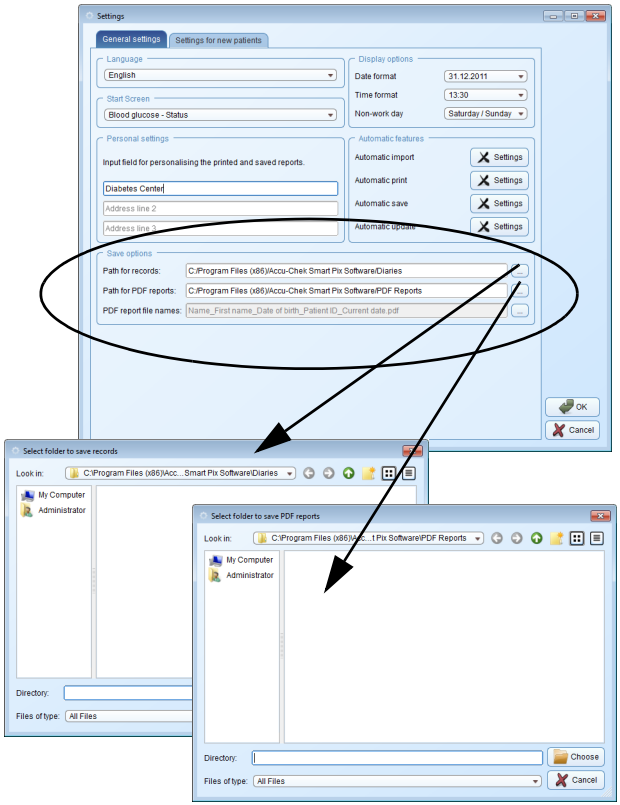
Personal settings

- Enter up to three rows of personal data (e.g., name and address of the medical institution). This text will then appear on all saved or printed reports. The number of characters per row may not exceed 50.



Display options

- Select the display format for date and time.
- Select the non-work days. These will then be highlighted in colour in the reports.

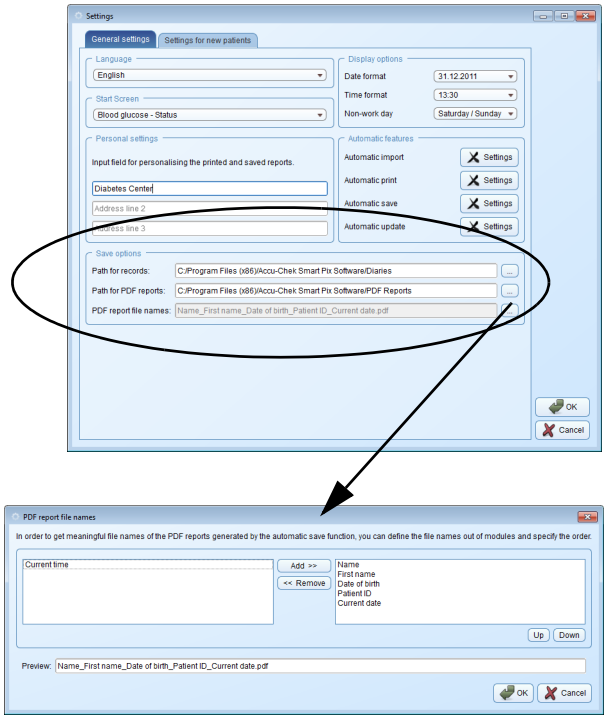


Save options

Here you select the folders where the newly created records and archived reports will be saved. The automatic features described in the following will also use these folders for saving data.

- Select the location you wish to use for saving the records.
- Select the location you wish to use for saving the archived reports (PDF files).

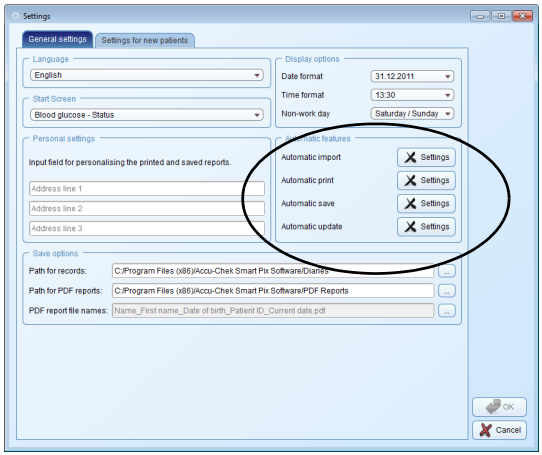
If you have installed the program on several individual computers in a network, please ensure that the settings configured here are identical for all computers. This is necessary to enable shared access to all records and archived reports.



In addition, you can configure the naming conventions to be used for future reports that are archived (as PDF files). You can combine several components in this file name to help you identify and sort the files later.

The *PDF report file names* dialog box displays two columns with possible components for the file name. The left column contains the components not currently used; the right column contains the components currently in use. The row below these columns previews the resulting name. You can change the composition of the name as follows:

- From the left column, select a component you wish to use, and click *Add*. The component will move to the right column.
- From the right column, select a component you no longer wish to use, and click *Remove*. The component will move to the left column.
- From the right column, select a component you wish to move to another position within the name. Click the *Up* or *Down* buttons to move this component up or down in the order.
- Click the *OK* button to save the entries.



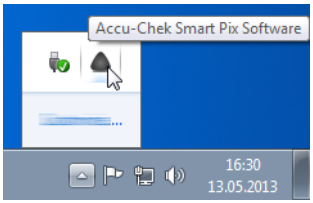
Automatic features

Automatic features help you simplify the following tasks:

- Importing device data and (if applicable) adding it to an existing record.
- Automatically printing device data.
- Automatically saving device data.
- Automatically download and install software updates.

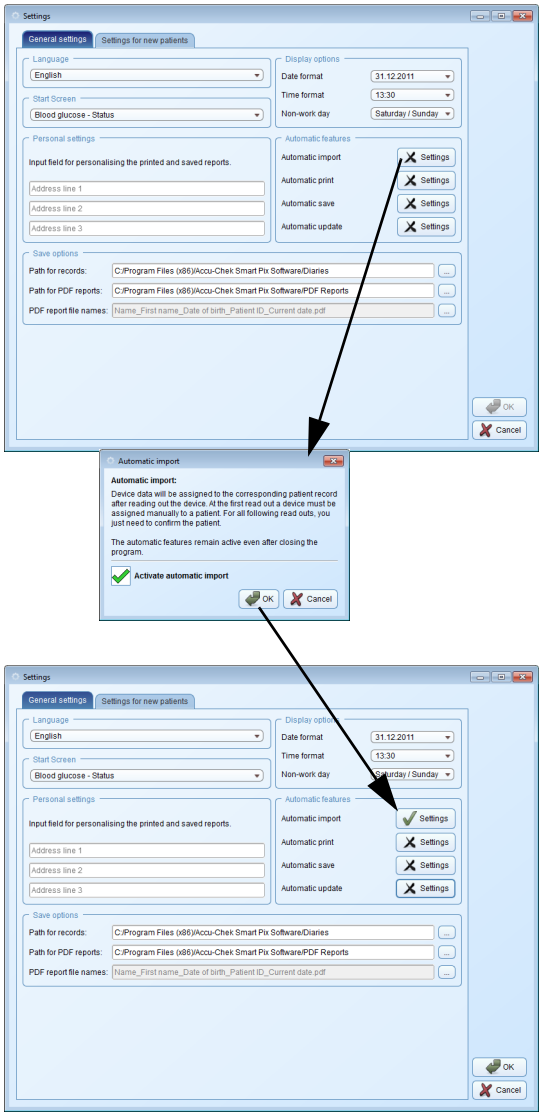
The term “record” encompasses all the data read from devices (with manual additions, if applicable) and assigned to a certain person. Data read from the device will always be saved (either to a new or an existing record) unless you select *No* when reading from the device. If, in such a case, you do not manually save the imported data later, it will only be displayed temporarily and will be deleted with the next import.

When importing data from a device for the first time, a new record can be created or the device can be assigned to an existing record. The data from further imports from the same device(s) is added to the existing data of that person.



If you have enabled one or more of the automatic features, the program will no longer close when you close the program window. You will be notified when the program launches as well as when the program window closes that the program will continue running in the background to continue providing the automatic features.

To completely close the program or to restore it to the foreground, right-click the Accu-Chek Smart Pix icon in the information area (right-hand side of the Windows taskbar) and select *Open* or *Quit*.



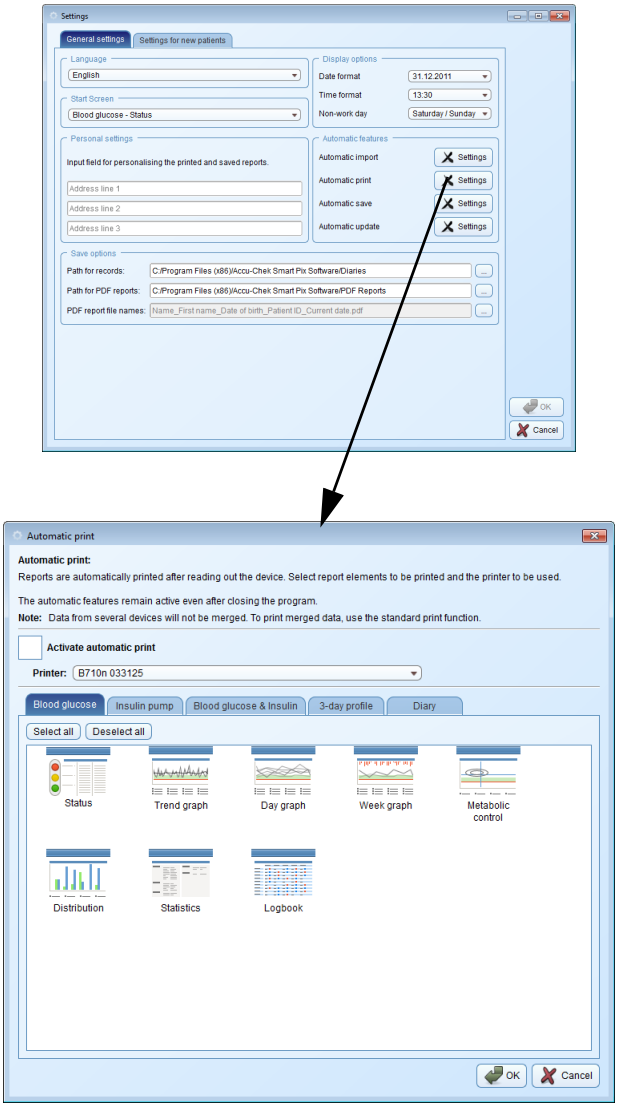
Automatic import

This feature ensures that data available in the Accu-Chek Smart Pix system is adopted directly and saved as a record.

- Click the *Automatic import* button.
- Click the *Activate automatic import* checkbox. A check mark will appear.
- Click the *OK* button to save the entries.

The *Automatic import* button will now be displayed with a check mark indicating that the corresponding feature has been activated. Deactivated features are displayed with a on their button.

The records will be saved in the folder you selected in *Save options* (see page 26).

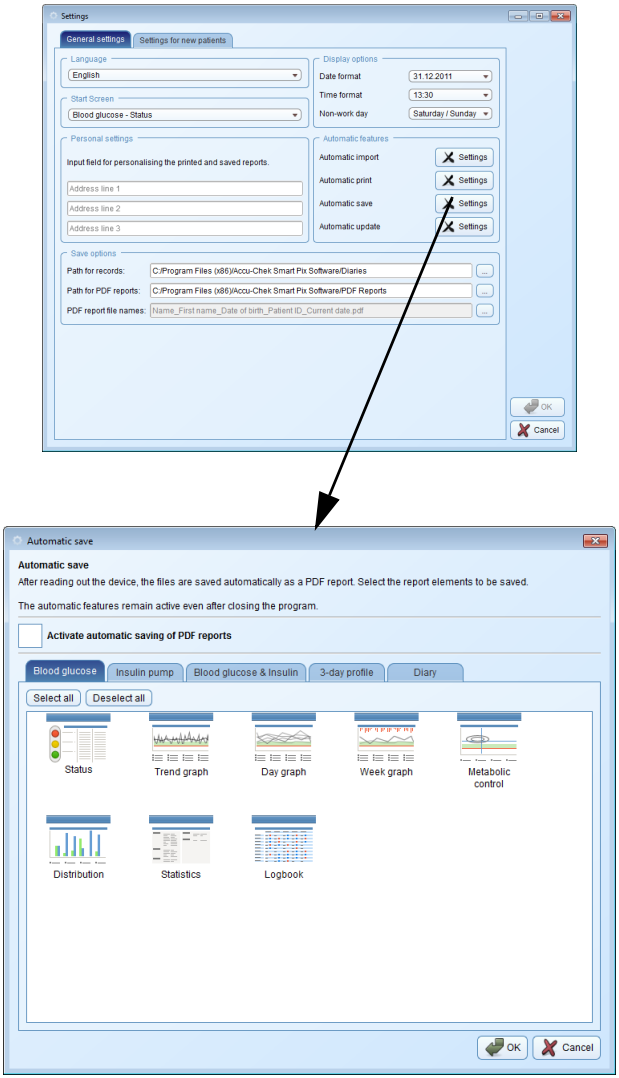


Automatic print

To use this feature, you need to select a printer available from the computer, as well as the reports to be printed.

- Click the *Automatic print* button.
- Click the *Activate automatic print* checkbox. A check mark will appear.
- Select the printer you wish to use.
- Select the report elements you wish to print. Click once to select a report element (it will be highlighted in blue); click the same report element again to undo your selection.
- Click the *Blood glucose*, *Insulin pump*, *Blood glucose & insulin, 3-day profile* and *Diary* tabs in succession to separately select the report elements to be printed for every one of these reports.
- Click the *OK* button to save the entries.

The *Automatic print* button will now be displayed with a check mark indicating that the corresponding feature has been activated. Deactivated features are displayed with a on their button.



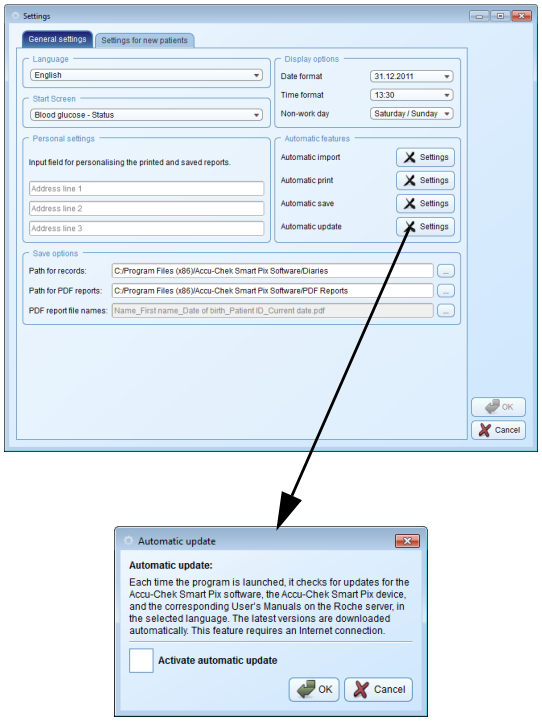
Automatic save

This feature will automatically save reports as PDF files and is independent of the saving feature for records, which is activated using automatic import.

- Click the *Automatic save* button.
- Click the *Activate automatic saving of PDF reports* checkbox. A check mark will appear.
- Select the report elements you want to save as a PDF file. Click once to select a report element (it will be highlighted in blue); click the same report element again to undo your selection.
- Click the *Blood glucose*, *Insulin pump*, *Blood glucose & insulin, 3-day profile* and *Diary* tabs in succession to separately select the report elements to be saved for every one of these reports.
- Click the *OK* button to save the entries.

The *Automatic save* button will now be displayed with a check mark indicating that the corresponding feature has been activated. Deactivated features are displayed with a on their button.

The PDF files will be saved in the folder you selected in *Save options* (see page 26).



Automatic update

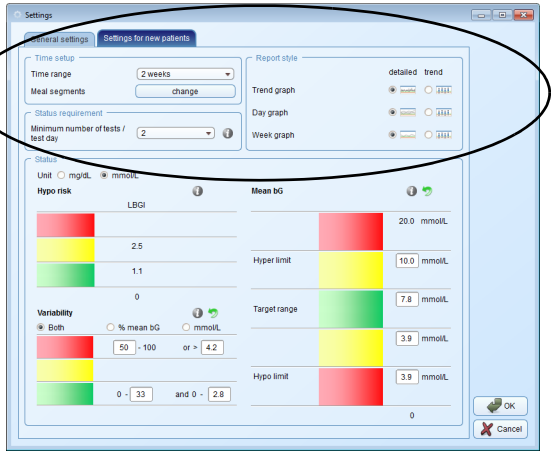
When this function is activated, the Accu-Chek Smart Pix software automatically checks whether updates are available for the Accu-Chek Smart Pix system (software, device reader, manual) every time the program starts. Current versions are automatically downloaded and (in a later step) installed.

- Click the *Automatic update* button.
- Click the *Activate automatic update* checkbox. A check mark will appear.
- Click the *OK* button to save the entries.

The *Automatic update* button will now be displayed with a check mark indicating that the corresponding feature has been activated. Deactivated features are displayed with a on their button.

Updating the respective components occurs as described below:

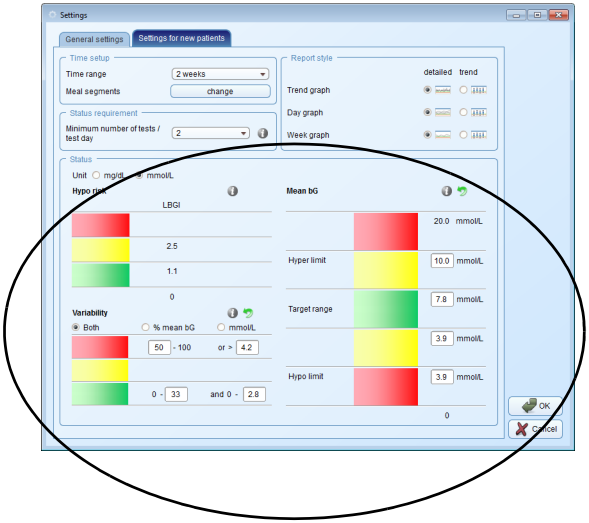
- The Accu-Chek Smart Pix software is updated at the next program start (after requesting confirmation).
- A connected Accu-Chek Smart Pix device is updated at the next program start (after requesting confirmation).
- The latest versions of the User's Manual are saved in the currently set language in the program folder in the *_Manuals* folder; older versions are deleted.



Settings for new patients

In the *Settings for new patients* window you will find configuration options for displaying reports. These settings will always be used when you are creating a new record.

- *Time range:* The *Time range* setting defines the number of days or weeks whose results will be displayed and analysed in the reports together.
- *Meal segments:* In some report elements, results are assigned to defined meal segments. These meal segments divide the day into eight periods typical for the patient, and they refer to meal or sleep times.
- *Minimum number of tests / test day:* A statistical analysis of *Hypo risk*, *Variability* and *Mean bG* can only be displayed if a minimum number of results per day exists. Select the minimum number of results from which to start displaying such statements in the *Status* report element.
- *Report style:* Some graphical report elements can be displayed in two different styles.



- *Status:* The statements and statistics displayed in the *Status* report element refer to specified target values or target ranges and the deviation of the measured values from these. Here you can define these target values and target ranges that will also be used in other report elements.
  - Select the *Unit* (mmol/L or mg/dL) to use for setting the *Target range* for blood glucose results.
  - Choose whether to set the *Variability* in "% mean bG" and/or as a fixed value ("mmol/L" or "mg/dL").
  - *Mean bG:* The representation of the mean blood glucose value (mean value of all blood glucose values in the selected time range) is defined by the upper and lower limit as well as the hypoglycaemia limit and the lower limit of the red area that indicates that the mean blood glucose is too high. By setting these limits, you determine the values that fall within the target range (green), above or below the target range (yellow) or below the hypo limit and above the lower limit of the red area that indicates that the mean blood glucose is too high.

If you wish to use the lower limit of the target range as an indicator of a possible hypoglycaemia (low blood glucose), it is important to remember the following: the indicator will only be reliable if the limit has been properly selected. We therefore strongly recommend that you talk to your healthcare professional before you set the limit. This function is no substitute for hypoglycaemia training by your healthcare professional or healthcare team.

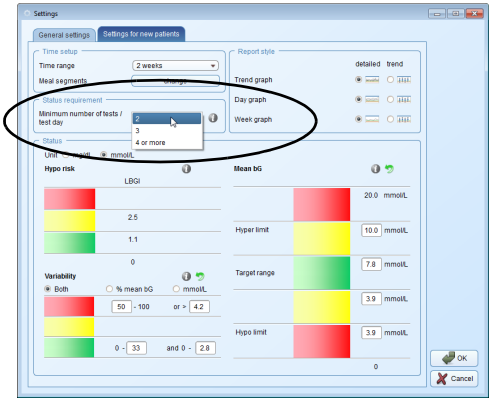
Time setup

Select the default *Time range* you want a report to analyse and display. You can change this setting at any time in reports as they are being displayed to examine them in more detail or with respect to more long-term developments. All displayed charts, values and statistics refer to the selected time range.

By setting *meal segments*, you divide a 24-hour day into eight periods which are determined by important regular events (e.g., main meals). For each meal segment, you can specify the start time while the end time is automatically the start time for the next period.

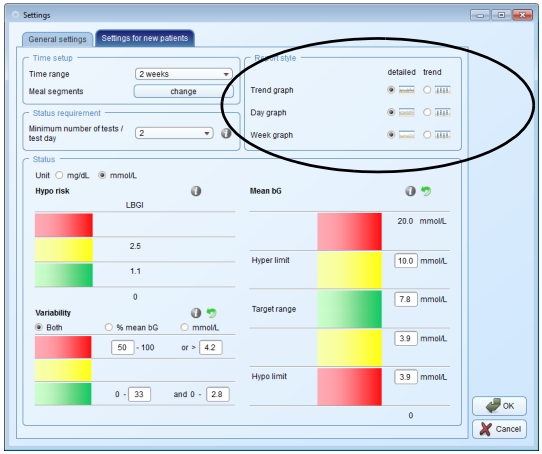
The meal segments set here are used in reports to structure them visually and chronologically.

- Click the *change* button to open the dialog box for setting the meal segments.
- You can set the time separately in hours and minutes using the arrow buttons, or enter the time directly as a number.
- Click the *OK* button to save the settings.



Minimum number of tests / test day

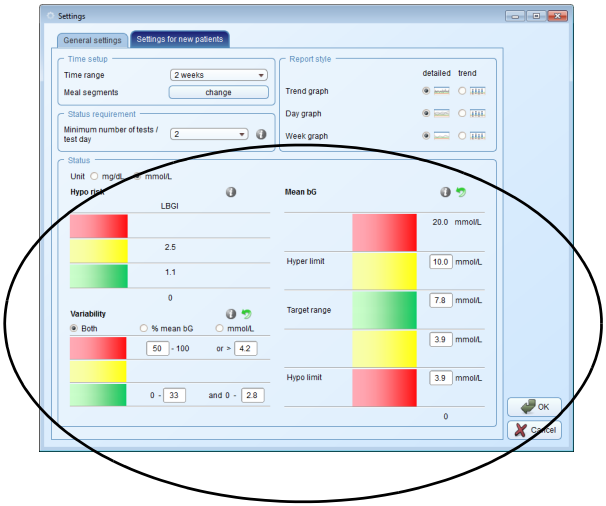
To gain meaningful results from statistical analyses, tests need to be conducted with a certain regularity (throughout the day) and frequency. Select the minimum number of tests necessary to display a statistical analysis. If the actual number of tests is below this value, the *Status* report will not display any information on the *Hypo risk*, *Variability* and *Mean bG*. This will always apply regardless of the selected setting if there is less than a total of 28 results.



Report style

Some graphical report elements can be displayed in two different styles. The main difference between these styles is their level of detail. Report elements in the *detailed* report style display precise trends including individual values. The *trend* report style allows easy interpreting of trends and developments (without showing individual values). You can set up the report style for the *Trend graph, Day graph* and *Week graph* report elements separately.

- For each report element, click the radio button with the report style you wish to use.

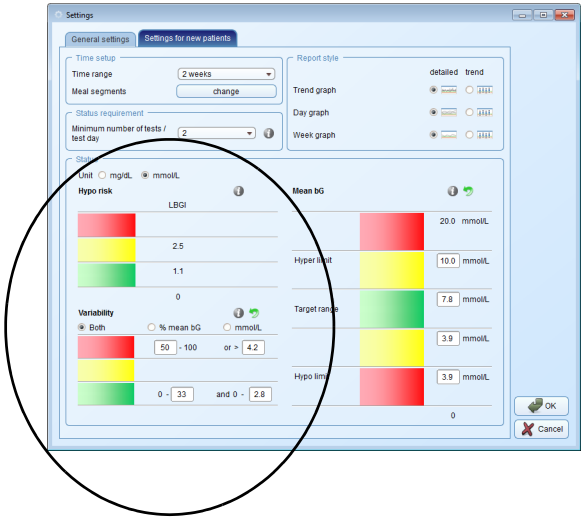


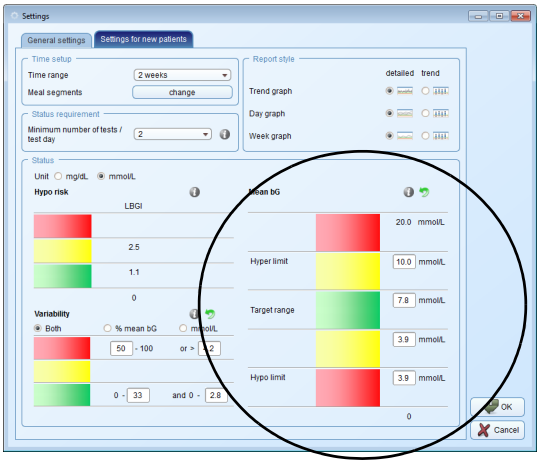
Status

The statements and statistics displayed in the *Status* report element refer to specified target values or target ranges.

There are three colours to graphically represent the results. The colours have the following meaning:

- **Green** means that the values fall within the target range.
- **Yellow** means that the values fall outside the target range.
- **Red** means that the values fall significantly outside the target range.

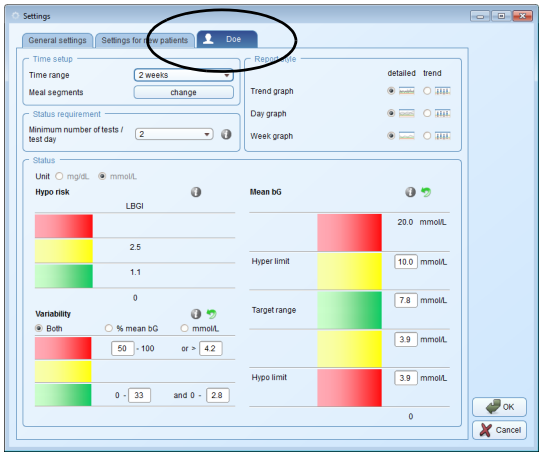




Each of the setup options given here refers to the limit separating the three areas mentioned above. This is shown by the colour bar above the respective input fields. The whole available setup area displays to the left and right of the input fields (e.g., 0 … 100 (%) if specified in percent; or 0 … 20 mmol/L if specified in mmol/L).

- Choose whether to set the *Variability* (standard deviation) in "% mean bG" and/or as a fixed value ("mmol/L" or "mg/dL").
- Select the limits (between the three areas) for *Variability*.
- In the *Mean bG* setup area, enter the values to be used for the lower limit of the red area that indicates that the mean blood glucose is too high, the upper and lower limit of the *Target range* and the *Hypo limit*, in the unit selected above. These are also the limits for the colour representation (green, yellow, red). The green area also defines the target range in the graphical report elements.

Click the button to display additional information about the respective term.
Click the button to reset the respective range to the default settings.



Customised settings for the patient record currently displayed

This window, whose name depends on the currently opened record, contains setup options for customising the report. The setup options are identical to the *Settings for new patients*.

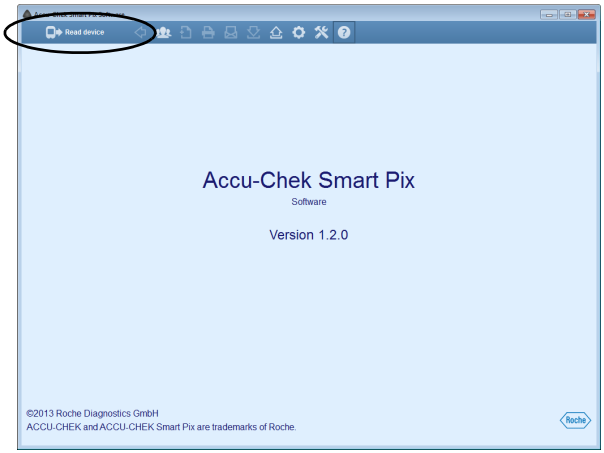
Use the setup area if you want to modify the settings for the patient record that is currently displayed. The changes made here are **only** applied to the currently opened record and saved with it.

4 Using the Accu-Chek Smart Pix software

The Accu-Chek Smart Pix software gives you the following options:

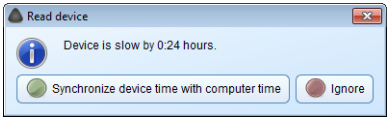
- Display reports with graphical, tabular and statistical elements.
- Maximise graphical report elements depending on the available screen area and examine them in detail.
- Interactively toggle individual graphics elements and/or adjust them.
- Save selected elements of a report as a PDF file for archiving.
- Print selected elements of a report.
- Email selected report elements.
- Display data read from the device as an Accu-Chek Smart Pix software record to edit and save it.
- Create records for multiple patients or users and assign the devices in use.
- Automate the reading, sending or saving of records and/or reports.
- Display archived (saved) reports in a PDF reader and print them.
- Perform software updates for the Accu-Chek Smart Pix device reader.

4.1 Manually reading data

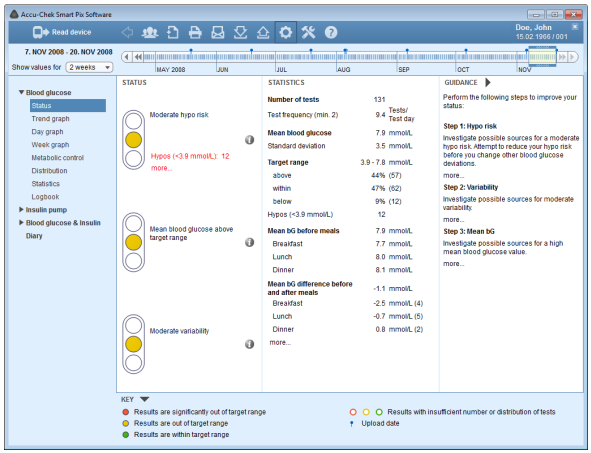


If you configured the Accu-Chek Smart Pix software so that **no automatic features** will run, you need to trigger the reading of data manually.

- Prepare the meter or insulin pump for transferring data. Please see the User's Manuals for the Accu-Chek Smart Pix device or the meter for detailed information about this preparation.
- Click the *Read device* button.

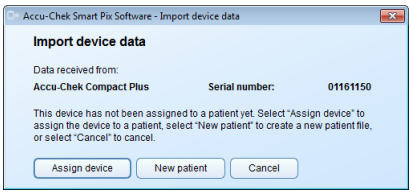


When reading the data, the time set in the device is compared to the time set in the computer. You will be notified if these times do not match. You can adjust the time set in the device directly (via the computer) if your meter supports this function.



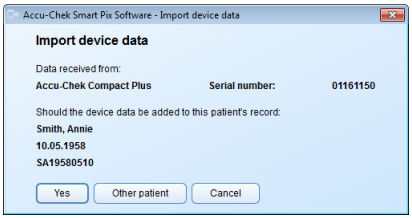
The data is now imported from the Accu-Chek Smart Pix device and prepared for a report according to the defaults. At this point in time the record is not yet saved. This allows you to simply display the report without assigning it to a patient and/or permanently saving it.

To permanently save the displayed record, click the *Save* button. Which dialog box will be displayed next depends on whether the respective device has already been assigned to a patient and/or record or not. Please see page 46 and further for information about creating and managing records.


Accu-Chek Smart Pix Software - Import device data
Import device data
Data received from:
Accu-Chek Compact Plus
Serial number: 01161150
This device has not been assigned to a patient yet. Select "Assign device" to assign the device to a patient, select "New patient" to create a new patient file, or select "Cancel" to cancel.
Assign device
New patient
Cancel

If data is imported from a device for the **first time**:

- The *Assign device* button allows you to add the data to an existing record.
- The *New patient* button allows you to create a new record and assign the device to it.



If data has already been imported from the device and assigned to a record:

- The *Yes* button allows you to confirm that the data is to be added to the existing and pre-selected record.
- The *Other patient* button allows you to assign the device to another existing record.

Please note that unsaved data is only available until you close the program or the record, or import new data.

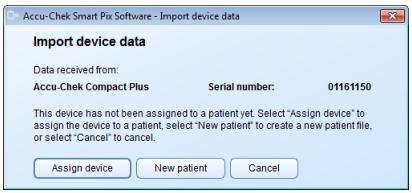
If patients are using several meters (e.g., one at the work place and one at home) and you want to read the data from all the devices for the same report, repeat the steps described above for each device.

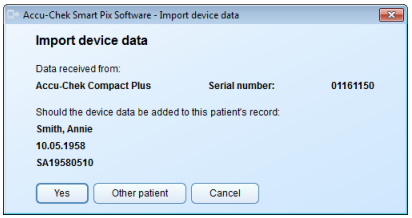
A joint analysis of several devices can only be performed if the imported data is saved. Reports that are not saved can only represent the data from one device.

To be able to analyse the combined data from several devices properly, all meters used should have the same date and time settings. Only then will the reports provide correct information for recommending a potential course of treatment.

4.2 Automatically reading data

If you configured the Accu-Chek Smart Pix software so that an *Automatic import* will be performed, it is not necessary for the program to run in the foreground. You can minimise or close the program window. As soon as the program running in the background recognises that new data has been transferred to the Accu-Chek Smart Pix device, you will be notified and guided through further steps.

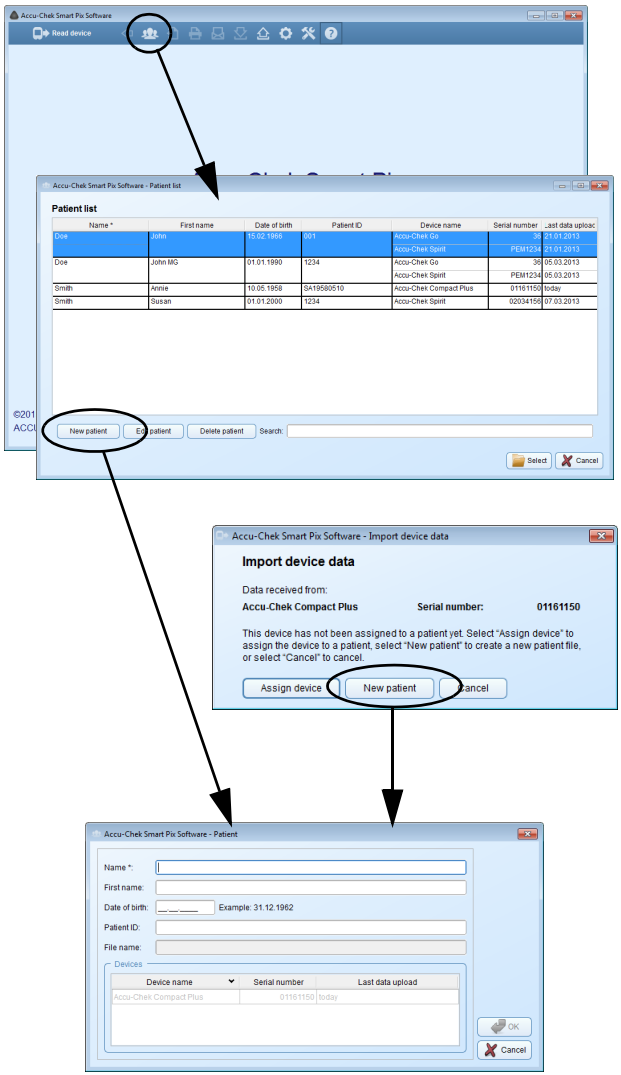

Accu-Chek Smart Pix Software - Import device data
Import device data
Data received from:
Accu-Chek Compact Plus
Serial number:
01161150
This device has not been assigned to a patient yet. Select "Assign device" to assign the device to a patient, select "New patient" to create a new patient file, or select "Cancel" to cancel.
Assign device
New patient
Cancel



As soon as new data is recognised, the following options can be taken as subsequent steps (as with manually reading data):

- If you have not yet created a personalised record for the currently imported data, you can create a new record for it and assign the device to it.
- If you have already created a personalised record but not yet assigned the device to it, you can assign it now.
- If you have already created the record and assigned the device to it, you will only need to confirm that the data is to be added to the record.
- You also have the option to view the data temporarily without saving it to a record.

4.3 Managing records



Creating a new patient record

You can create a new record at any time (independent of existing data), even during an import.

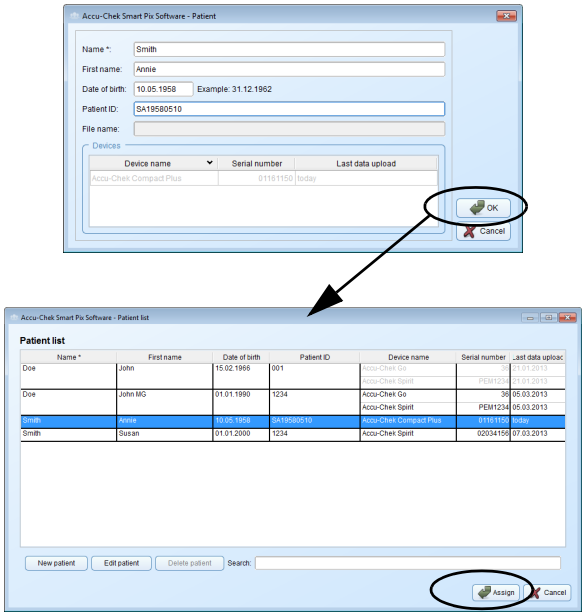
To create a new record:

- If there is no import running at the moment, click the *Patient list* button.
- In the *Patient list* window, click *New patient*.

Or:

- When the import dialog box is displayed, click the *New patient* button.

In the *Patient* dialog box displaying now, you need to enter at least the patient's name. Further identifying information such as first name, date of birth, or an existing patient ID are also possible and/or necessary if several patients with the same name exist.



To create the new record:

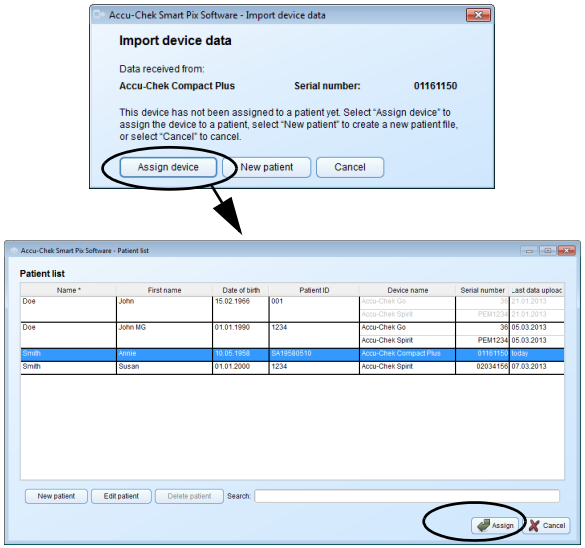
- Enter the name and any further information you require. You can use any of the information entered here if you want to search the record at a later stage.
- Click the *OK* button to create the record and to close the dialog box, or:
- Click the *Cancel* button to discard the modified entries and to close the dialog box without saving the changes.

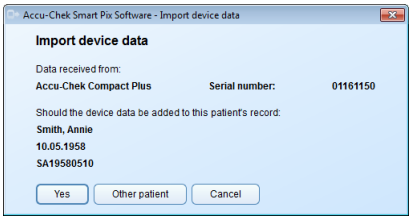
The meter entry visible in the above image is only displayed if this dialog box is opened during the import. Otherwise the device is assigned at a later stage.

If you have created the new record during an import, you will need to assign the device just read to this record to complete the process.

- Make sure you have the correct (newly created) record selected.
- Click the *Assign* button.

The device has now been assigned to this record. From now on, you will only need to confirm this connection when performing an automatic import. The data will be saved to the selected record.


Accu-Chek Smart Pix Software - Import device data
Import device data
Data received from:
Accu-Chek Compact Plus
Serial number:
01161150
This device has not been assigned to a patient yet. Select "Assign device" to assign the device to a patient, select "New patient" to create a new patient file, or select "Cancel" to cancel.
Assign device
New patient
Cancel
Accu-Chek Smart Pix Software - Patient list
Patient list
New patient
Edit patient
Delete patient
Search:
Assign
Cancel



Assigning an existing record

If you are importing data that is to be assigned to a person with an already existing record (e.g., if a new meter is used), you can do this during the import.

- Click the button.
- Click the *Assign device* button in the dialog box displayed.
- Make sure you have the correct record selected.
- Click the *Assign* button.

The device has now been assigned to this record. From now on, you will only need to confirm this connection when performing an import. The data will be imported and saved to the selected record.

Confirming the device assignment

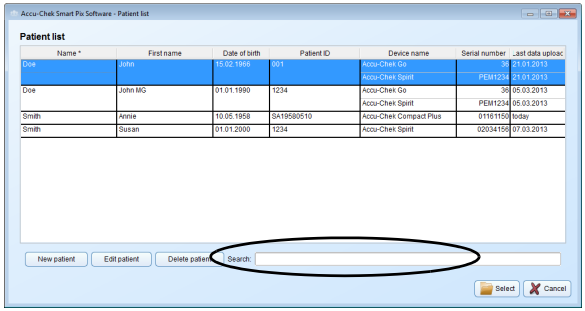
If the assignment has already been completed, it will be displayed when saving future imports.

- Click the *Yes* button to add the data to the existing record.

The data will be saved to the selected record.

- Click the *Other patient* button to re-assign the device.
- Click the *Cancel* button to close the dialog box without saving the data.

4.4 Further report and record management features



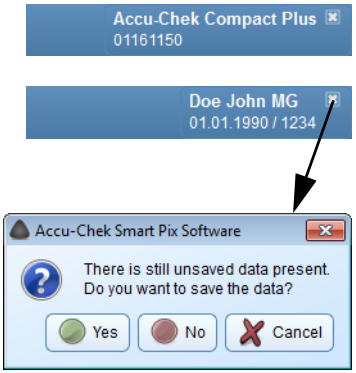
Opening a record

You can open saved records at any time. An opened record gives you access to all its reports and a tabular representation of its data (*Diary*).

- Click the *Patient list* button.
- Click the record you want to select it.
- Click the *Select* button.

To quickly find a certain record, you can also enter known parts of the patient ID into the search window on the bottom right. Only records matching these entries will be displayed.

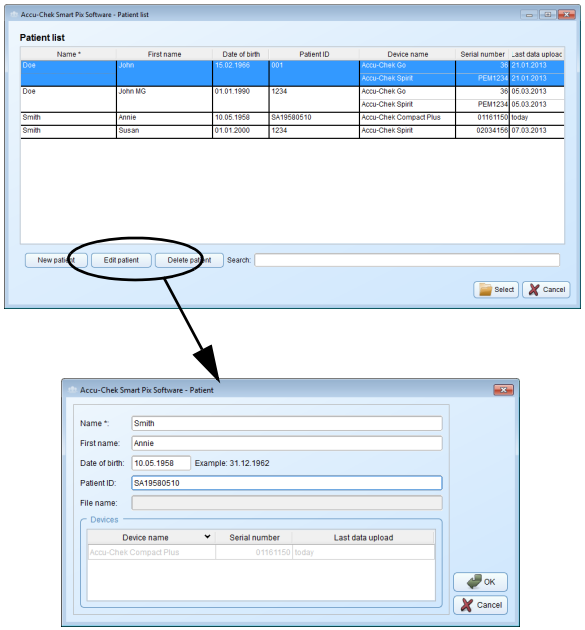
Closing the record and report



To close an open record (and/or the currently displayed report):

- Click the icon next to the record ID or the meter information.
- If the displayed data has not been saved yet, you will need to confirm whether you want to save or discard the data now.

Please note that unsaved data is only available until you close the program or the record, or import new data.

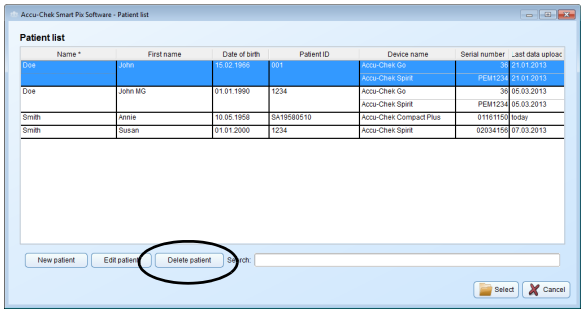


Editing a record

You can edit the name of a record at a later stage.

- Click the *Patient list* button.
- Click the record you want to select it.
- In the *Patient list* window, click *Edit patient*.
- Make the desired changes.
- Click the *OK* button to save the changes and to close the dialog box, or:
- Click the *Cancel* button to discard the modified entries and to close the dialog box without saving the changes.

You cannot use this feature to edit the information contained in this record. For more information about editing this information, please see page 113 and further.



Deleting a record

You can delete a record at any time.

The selected record will be deleted upon confirmation. Be sure that you no longer need the selected record. Regular data backups also help to avoid inadvertent data loss.

- Click the *Patient list* button.
- Click the record you want to select it.
- In the *Patient list* window, click *Delete patient*.

The selected record has now been deleted.

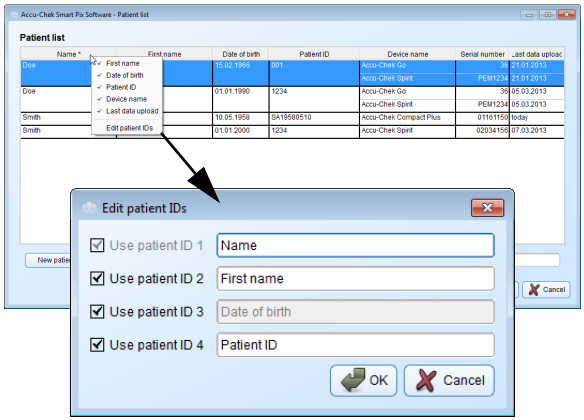
Archiving a record

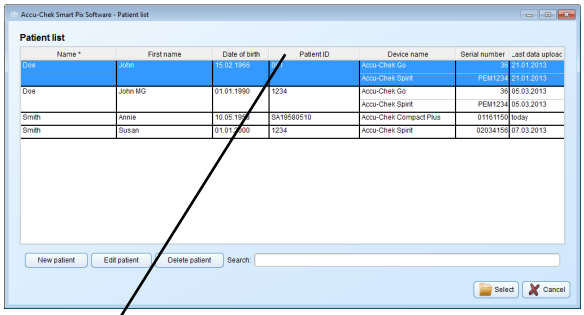
You can archive records (*.DIA) by copying the complete *Diaries* folder containing the saved records during your regular data backups.

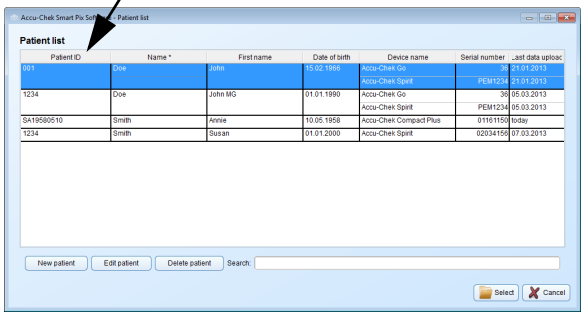
Please see page 61 and further for information about reading such an archived record.

Adjusting the patient list display

You can toggle the contents displayed in the patient list as you wish and you can also rename the column headings.



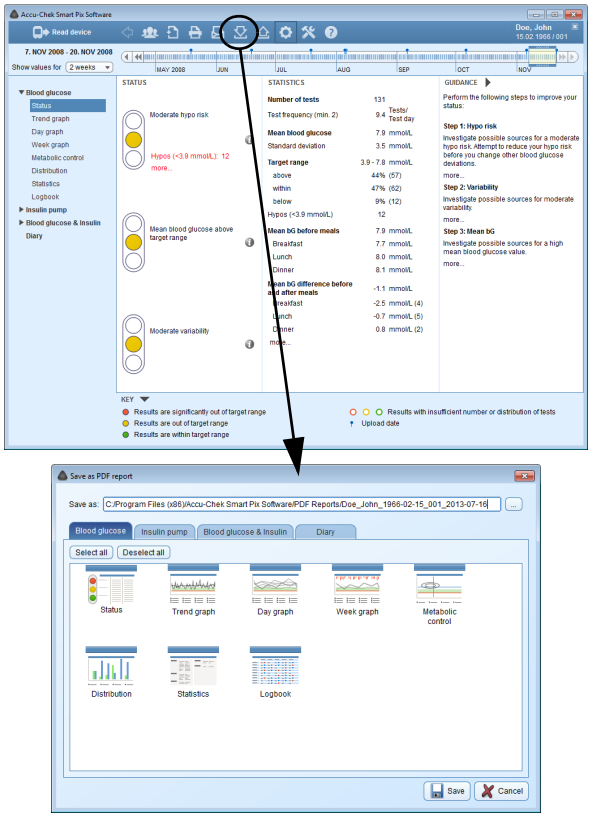




- Right-click any column heading.
- From the context menu, select the contents you want to display in the patient list (check mark). Remove the check mark for contents you want to hide. ID1 (name) will always be displayed and cannot be hidden.
- From the context menu, select *Edit patient IDs* if you want to change the column heading (e.g., *Name*, *First name*).
- If you categorically do not wish to use one individual ID, deselect the checkbox to the left. The respective ID will be hidden from the patient list and the *Patient* dialog box. ID1 (Name) will always be displayed and cannot be deactivated.
- Click on a column heading and drag it to any position to change the display sequence of the IDs.
- Click any column heading to sort the table by this column.
- Click on the column heading according to which to sort the patient list. Click the ⌄ button next to the selected column heading to toggle the sorting order (ascending or descending). You can, e.g., sort according to the date when data was last read from the device and then all records changed on the current date can be found at the beginning (or end) of the list.

If there are several records with the same information (e.g., the current date) for the selected sorting basis (e.g., date when data was last read from the device), the resulting group will be sorted also by name.

4.5 Exporting reports as PDF files



When you have read device data or opened a record, you can save the displayed report as a PDF file.

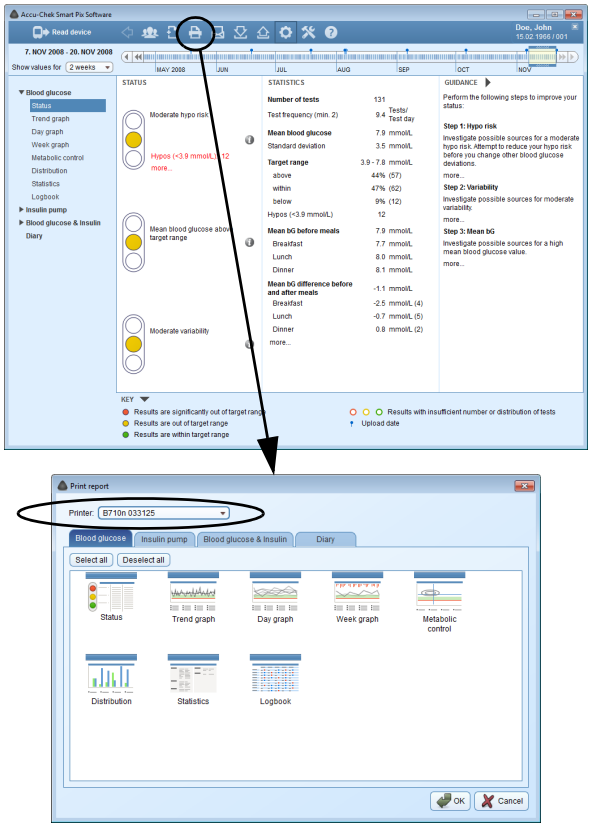
- Click the button to save selected report elements. The selection window will be displayed.
- Enter the desired file name in the corresponding input field. You can also keep the default file name (see *Save options* in chapter 3). The file will be given the name entered here along with the suffix ".pdf".
- From the displayed reports (displayed on four tabs) and report elements, select the ones you want to save in the file. Selected report elements are highlighted in colour.
  - To select an individual report element, click the corresponding report icon. To select all the report elements, click the *Select all* button.
  - To deselect a highlighted report element, click the report icon again. To deselect all highlighted report elements, click the *Deselect all* button.
- When you have selected all the desired report elements, click the *Save* button.

This creates the PDF file and saves it in the folder selected in *General settings*. If you decide not to save the file, click the *Cancel* button instead.

4.6 Printing reports

When you have read device data or opened a record, you can print the displayed report with the Accu-Chek Smart Pix software's print feature.

- If you are printing a currently **displayed report** (regardless of whether it is new or created from a currently opened record), you will be given the selection options described below.
- If you have opened an **archived report** saved as a PDF file (see page 59), displaying and printing it occur using the respective functions of the PDF program installed on your computer. This is not part of the Accu-Chek Smart Pix software.



To print a report:

- Click the button to print selected report elements. The selection window will be displayed.
- Click the printer you wish to use for printing the report elements.
- From the displayed reports (displayed on four tabs) and report elements, select the ones you wish to print. Selected report elements are highlighted in colour.
  - To select an individual report element, click the corresponding report icon. To select all the report elements, click the *Select all* button.
  - To deselect a highlighted report element, click the report icon again. To deselect all highlighted report elements, click the *Deselect all* button.
- When you have selected all the desired report elements, click the *OK* button.

The selected report elements are now output to the selected printer. If you decide not to print the file, click the *Cancel* button instead.

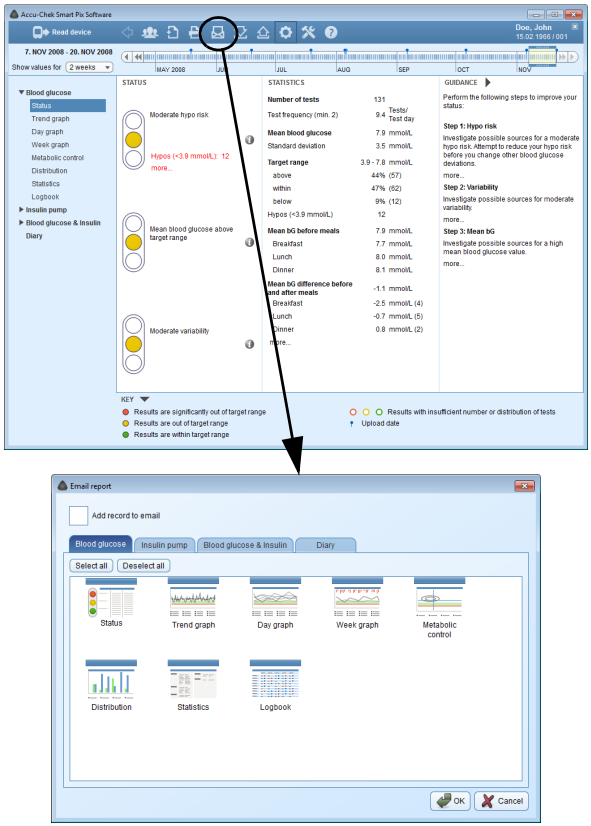
4.7 Emailing reports

When you have read device data or opened a record, you can directly email the displayed report.

A suitable email program must be installed and configured on your computer to be able to use this function.

This feature will automatically create a PDF file of the selected report elements, opens your email program and creates a new email with the PDF file as an attachment. In addition, you can attach the record (*.DIA) used as the basis for this report. Please see page 61 for information about reading such a record received by email.

Independently of this, you can send reports previously exported as PDF files as email attachments (you do not need the Accu-Chek Smart Pix software for this).



To email a report:

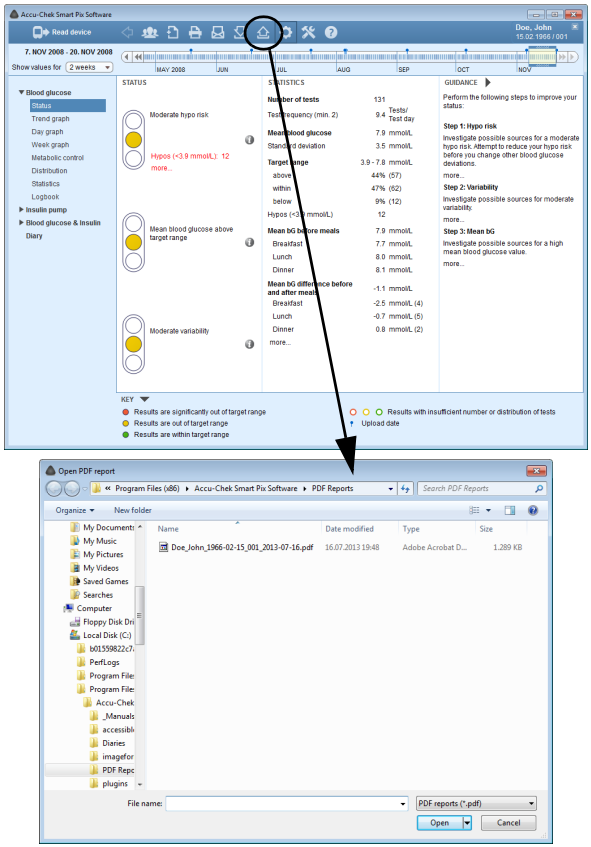
- Click the button to send selected report elements. The selection window will be displayed.
- Select the corresponding checkbox if you want to add the complete record (*.DIA) as well.
- From the displayed reports (displayed on four tabs) and report elements, select the ones you wish to send. Selected report elements are highlighted in colour.
  - To select an individual report element, click the corresponding report icon. To select all the report elements, click the *Select all* button.
  - To deselect a highlighted report element, click the report icon again. To deselect all highlighted report elements, click the *Deselect all* button.
- When you have selected all the desired report elements, click the *OK* button.

The selected report elements are now saved to a temporary PDF file (which will be deleted after the email is sent). If you decide not to send the report elements, click the *Cancel* button instead.

Your computer's default email program is then launched and an empty email is opened. The email subject line is already filled in (but you can change the text if you want). The PDF file just created and the record (if selected) are enclosed as an attachment.

- Enter the email address of the recipient.
- Write a text referring to the report attached.
- Send the email.

4.8 Displaying archived reports (PDF files)



All the reports you have previously exported (archived) as a PDF file using the button can be opened in the Accu-Chek Smart Pix software at any time.

The exported PDF files are displayed using the PDF reader (e.g., Adobe Reader) installed on your computer, not in the Accu-Chek Smart Pix software. This is why you can also forward these PDF files to someone not working with the Accu-Chek Smart Pix software for information purposes.

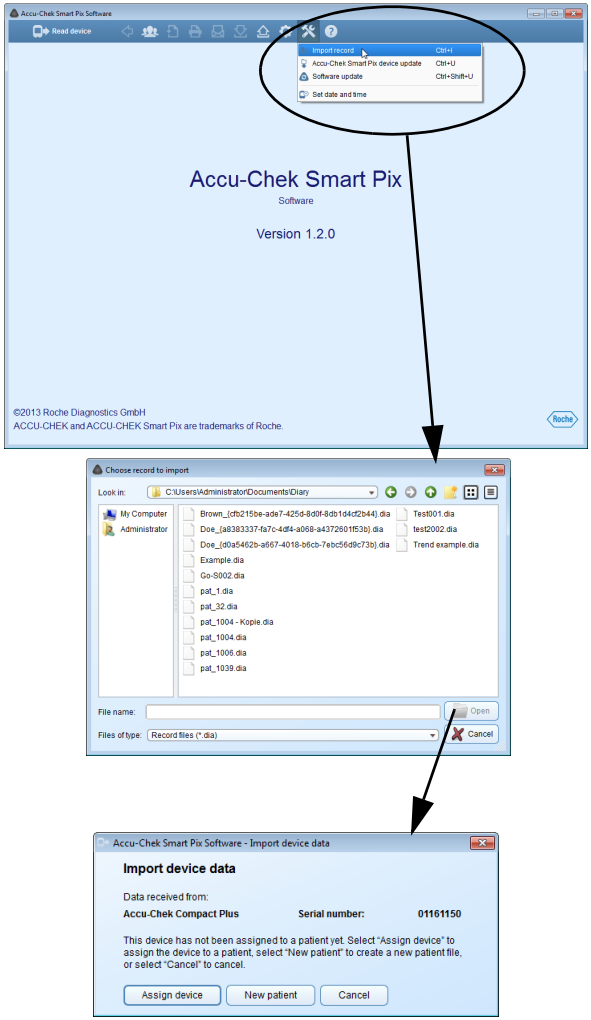
- Click the button to open an archived PDF file.
- Select the file you want to use from the dialog box now displaying.
- Click the *Open* button.

The PDF reader will now launch and display the selected PDF file. All the display and print options available here depend on the installed program.

4.9 Special functions

The Accu-Chek Smart Pix software allows you to select the following special functions:

- Importing externally available records (*.DIA) and assigning them to a patient
- Performing updates for the Accu-Chek Smart Pix device
- Manually trigger the search for software, device and User's Manual updates
- Setting date and time of the majority of supported blood glucose meters
- Other additional functions which may be available in the future via an add-on module.



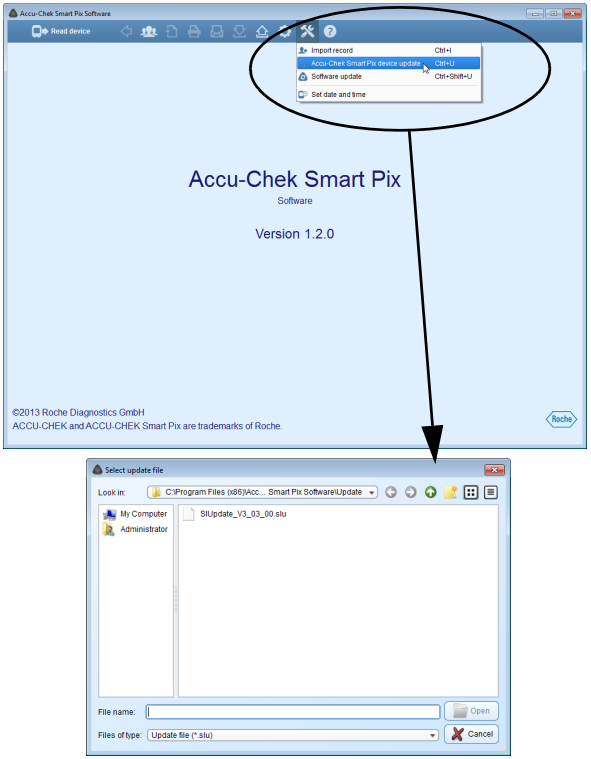
Importing records

To add a DIA file which was received by email or restored from a data backup to your patient list:

- Click the *Tools* button.
- Select the *Import record* option.
- In the following dialog box (if there is more than one file), select the desired DIA file and click *Open*.

Now the same dialog box will be displayed as the one displayed when reading data from an unknown meter. You can now assign the contents of the file for import to a new or an existing record.

When importing a DIA file to an existing record, duplicates (i.e., entries that have been read previously) are kept and only new entries are added.



Performing updates for the Accu-Chek Smart Pix device

The program folder of the Accu-Chek Smart Pix software also contains the Accu-Chek Smart Pix device system software which is current at the time of delivery. This software can be installed using the *Accu-Chek Smart Pix device update*, provided the Accu-Chek Smart Pix device is plugged in.

- Click the *Tools* button.
- Select the *Accu-Chek Smart Pix device update* option.
- In the following dialog box (if there is more than one file), select the desired version and click *Open*.

The software update will now be installed. In the meantime, the Accu-Chek Smart Pix device logs itself off and logs in again (if the update has been successful).

You can find the User's Manual for the latest version of the Accu-Chek Smart Pix system in the Accu-Chek Smart Pix program folder. Open the *Manuals\Accu-Chek Smart Pix Device Reader Manuals* folder and select the User's Manual for your language.

Search for software updates for the Accu-Chek Smart Pix system

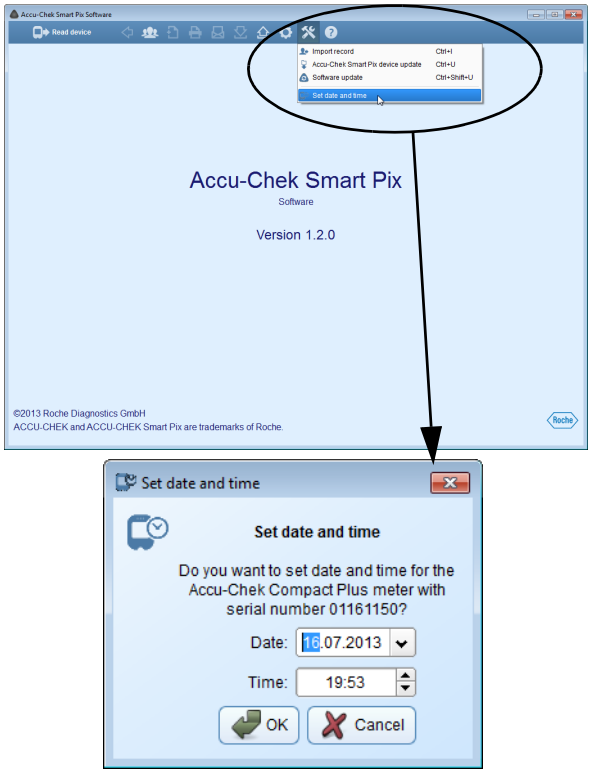
If you have not configured the software to automatically search for available updates at every program start, you can manually trigger the search with this function. This is useful, e.g., if the computer is not regularly connected to the Internet.

- Click the *Tools* button.
- Select the *Software update* option
- Click on *Yes* to launch the search for current software versions.

The search is performed in the background and you can use the Accu-Chek Smart Pix software without restriction. When a more current version is found, it is downloaded.

Updating the respective components occurs as described below:

- The Accu-Chek Smart Pix software is updated at the next program start (after requesting confirmation).
- A connected Accu-Chek Smart Pix device is updated at the next program start (after requesting confirmation).
- The latest versions of the User's Manual are saved in the currently set language in the program folder in the *_Manuals* folder; older versions are deleted.

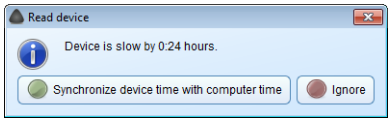


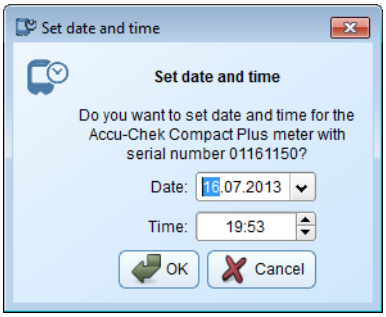
Setting date and time in the meter

For the majority of supported meters, you can set date and time directly from the Accu-Chek Smart Pix software. You can correct this manually at any time or when you are notified during the reading of data that there is a mismatch between the times on the meter and on the computer.

Manually correcting date and time

- Click the *Tools* button.
- Select the *Set date and time* option.
- Prepare the meter for communication as shown in the following dialog box.
- If the meter allows you to set date and time, you can accept the date and time displayed in the following dialog box or adjust it as you wish. You will be notified if your meter does not support this function.
- Click the *OK* button to send the settings to the meter.




Set date and time
Set date and time
Do you want to set date and time for the Accu-Chek Compact Plus meter with serial number 01161150?
Date: 16.07.2013
Time: 19:53
OK
Cancel

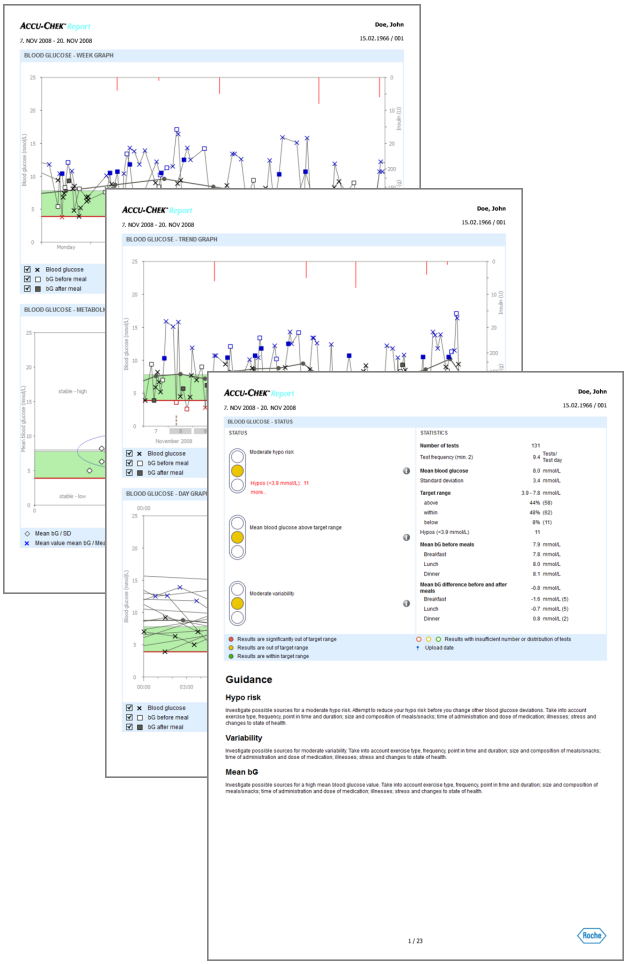
Semi-automatically correcting date and time

When you are reading data from a meter, the Accu-Chek Smart Pix software will automatically compare the date and time settings of the meter with those of the computer. If the device meter cannot be set directly, you will be notified of the difference between the meter and the computer in case there is a deviation. In this case, make the correction directly on the meter.

- If the meter allows you to set date and time, you can accept the date and time displayed in the associated dialog box or adjust it as you wish.
- Click the *OK* button to send the settings to the meter.

5 Reports and records

5.1 Blood glucose: general information about the reports



Types of reports

The Accu-Chek Smart Pix software creates single-page or multi-page reports for defined periods (e.g., the last 2 or 4 weeks). The style was defined during configuration; the period can be selected as needed. A blood glucose report can always contain any of the following report elements:

[1] Status
[2] Trend graph
[3] Day graph
[4] Week graph
[5] Metabolic control
[6] Distribution
[7] Statistics
[8] Logbook

The illustration on the left shows examples of reports, either available as a printout or exported as a PDF file.

Analysed data

The Accu-Chek Smart Pix software checks the read data to create the reports. The following data is not included in the statistics:

- Test results outside the selected time range
- Test results saved without date and time
- Tests with control solution
- Invalid/deleted tests
- Tests outside the measuring range (marked as HI/LO)

Existing target range definitions are only adopted from the Accu-Chek Pocket Compass software. Apart from that, the settings made during configuration of the Accu-Chek Smart Pix software apply.

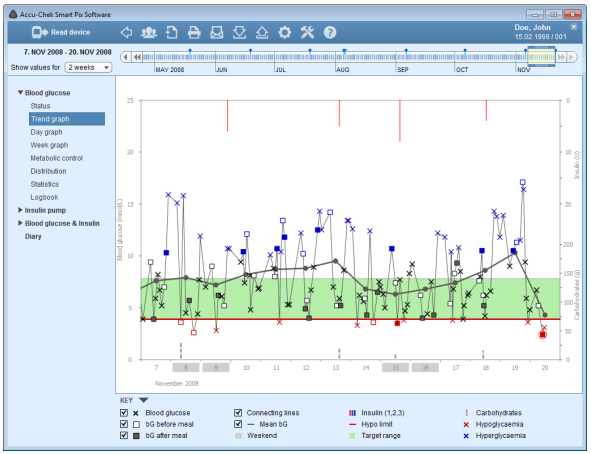
Please note the following when using the Accu-Chek Smart Pix software with several meters and patients:

To ensure that the report belonging to a particular meter is displayed, compare the serial number on the meter with the data displayed in the top right-hand-corner of the report, e.g., patient name or meter name and serial number.

Report styles

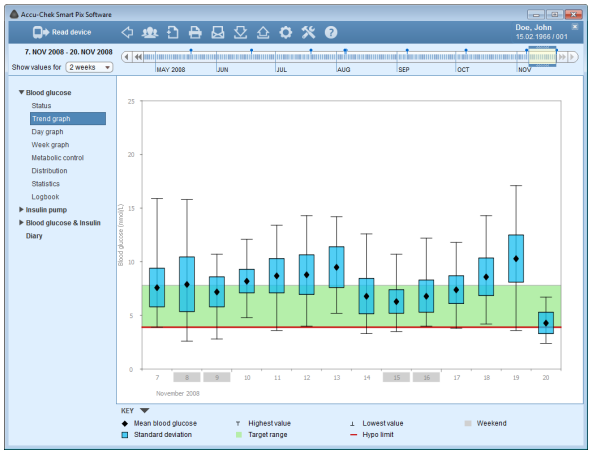
For some report elements, a style is defined during configuration, either *detailed* or *trend* . These two styles offer different types of presentation for identical information. You can select either of these styles for each of the following report elements:

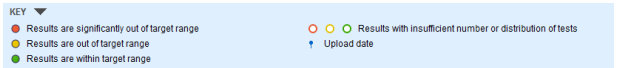
- Trend graph
- Day graph
- Week graph



Detailed All results will be displayed in the chart as linear values. Each test result is plotted along the time axis according to the time when the test was performed. Test results performed within a 10-hour period are connected by a line. This creates (angular) “curves” which, together with the actual test result entry, allow you to obtain a detailed analysis of individual results and trends.

Insulin and carbohydrate amounts (displayed at the top and bottom of the chart, if transferred by the device or manually entered into the list) can only be displayed in this report style.




KEY
Results are significantly out of target range
Results are out of target range
Results are within target range
Results with insufficient number or distribution of tests
Upload date

Trend Within the chart, all results are arranged in a coarse time grid (consisting of days, days of the week, or meal segments). Mean blood glucose value, standard deviation as well as the highest and lowest test result will be displayed. This does not allow a selective analysis of individual results but it facilitates identification of general trends within the time grid.

Graphical elements of the reports

In all reports, you will find legends explaining the meaning of individual elements. In the following, you will find detailed explanations of the various elements.

Icons *(Detailed)* Test results are plotted in the report elements using various icons to increase their level of information:

Mean blood glucose

Blood glucose value without any additional information. Results below the hypo limit are shown in red; results above the hyper limit are shown in blue.

Blood glucose value before or after meal. Results below the hypo limit are shown in red; results above the hyper limit are shown in blue.

Result outside the measuring range (indicated on the meter as HI or LO).

Blood glucose value above 25 mmol/L or 400 mg/dL.

Blood glucose value (any icon inside the red circle) accompanied by hypoglycaemic symptoms.

Blood glucose value (any icon inside the black circle) with a user-defined event (marked with an asterisk * on the blood glucose meter).

Insulin amount for insulin 1 ▮, 2 ▮ or 3 ▮, respectively. Insulin amounts are plotted in the chart top down.

Carbohydrate amounts; represented at the bottom in some report elements. The carbohydrate amount is indicated by the height of a single block (or a bar consisting of several blocks). The bars shown in this illustration (from left to right) represent the following amounts:

– Block 1: 2.5 g

– Block 2: 5.0 g

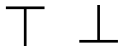
– Block 3: 7.5 g

– Bar 4 (3 blocks of 10 g each): 30 g

Icons (*Trend*) Here the analysis does not cover individual test results but mean values in relation to a certain time grid. Here you will find the following icons:

Mean blood glucose

Standard deviation



Highest result and/or lowest result

Maximum value/minimum value outside the measuring range (HI/LO).

Icons (Record) The following additional icons are used in the tabular representation:

User-defined event, e.g., Alternative Site Testing (AST)

Hypoglycaemia

Carbohydrate amount

Before/during/after exercise

Stress

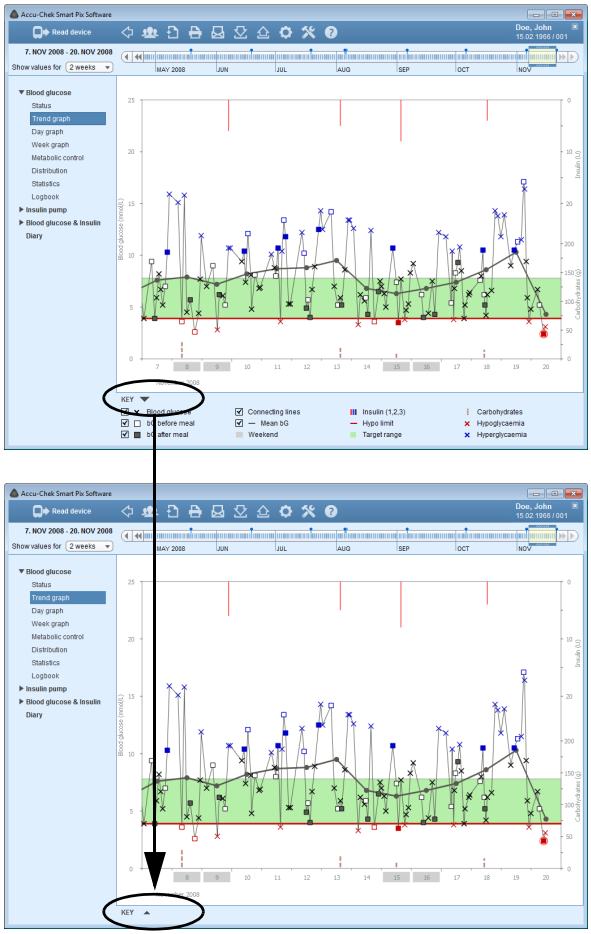
Illness

Test results which have been imported from the Accu-Chek Pocket Compass software or from Accu-Chek Aviva Combo, Accu-Chek Aviva Expert, Accu-Chek Performa Combo or Accu-Chek Performa Expert meters may include several items of additional information (events) which are not represented by icons. These events are displayed in the comments column of the list representation:

- Snack
- Bedtime
- Fasting
- Before exercise
- After exercise
- Stress
- Illness
- Oral medication
- User-defined
- Hypo warning
- Hyper warning
- Premenstrual
- Other
- Exercise 1
- Exercise 2
- Manually entered value

The icons previously described are used for all other events.

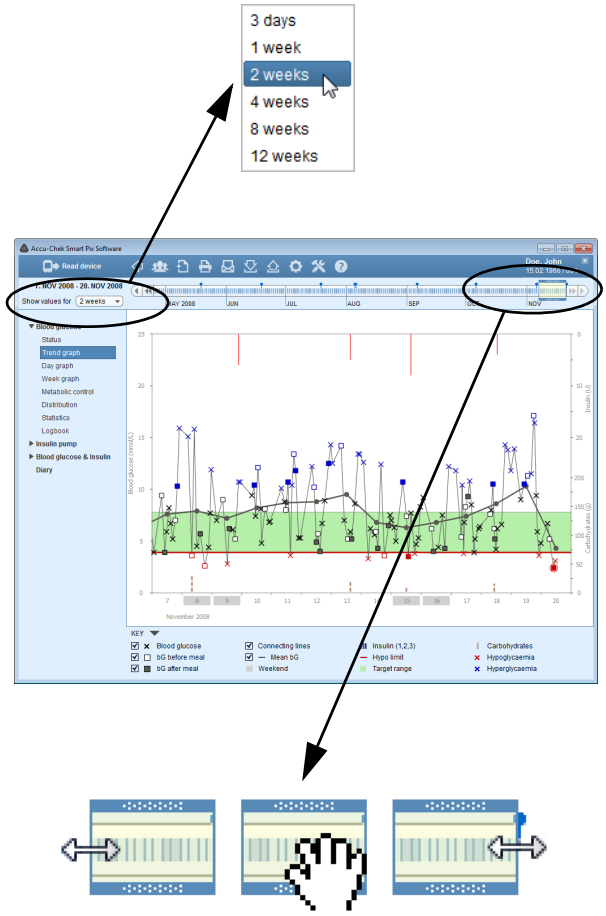
5.2 Interactive features in the report



The reports displaying on-screen contain many interactive features you can use to directly modify the representation. These features help you to, e.g., see certain information in more detail or to hide interfering elements.

Toggling panes

Whenever you see this triangular icon ▼ in a report, you can click it to toggle its associated panes. This allows you to, e.g., create more space for graphical representations by hiding the legend.



Changing the time range

In the beginning, every report shows the time range set in the configuration, with the most current data at the end of the visible range.

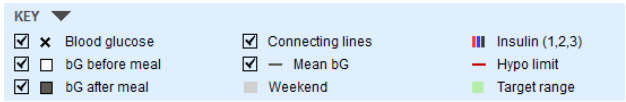
To change the time range at a click, simply select a default time range using the associated button.

The interactive time axis allows you to easily navigate all available data thanks to a moveable time range.

The frame highlighted in yellow shows the currently selected section on the time axis.

- You can enlarge or reduce this frame at the left and right edge to adjust the displayed time range (by days, from 3 days to 12 weeks).
- You can move the whole frame along the time axis to go forwards or backwards in time.
- You can click anywhere in the time scale; the complete time range will then move its end point to the place where you clicked.
- You can use the arrow buttons at either end of the time scale to move the section by one day or one time range.

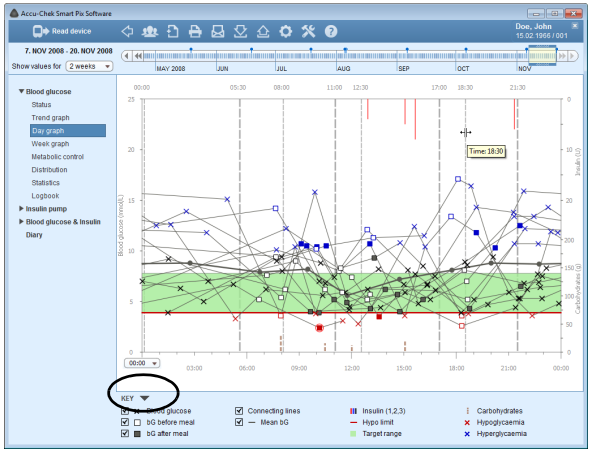
The screen representation of the report is immediately adjusted to the changes made to the time axis.



Changing chart contents

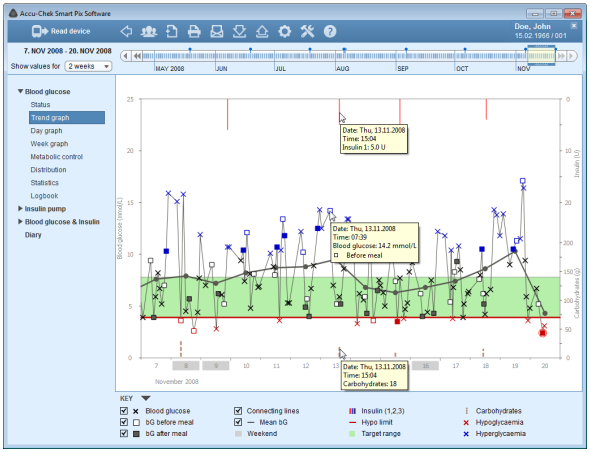
The *Trend graph*, *Day graph* and *Week graph* report elements allow you to toggle certain displayed objects and, in some cases, to change parameters of the representation:

- You can toggle each element which has a check mark in the legend by clicking this check mark.



In addition, you can change the time axis and the preset meal segments in the graphic report element *Day graph*:

- Select the starting time point of the (horizontal) time axis.
- Move your mouse across one of the vertical dotted lines separating two meal segments. When the mouse pointer turns into a double-pointed arrow, you can click and pull the line to move it horizontally to change the adjoining meal segments. A tooltip shows you the corresponding time.



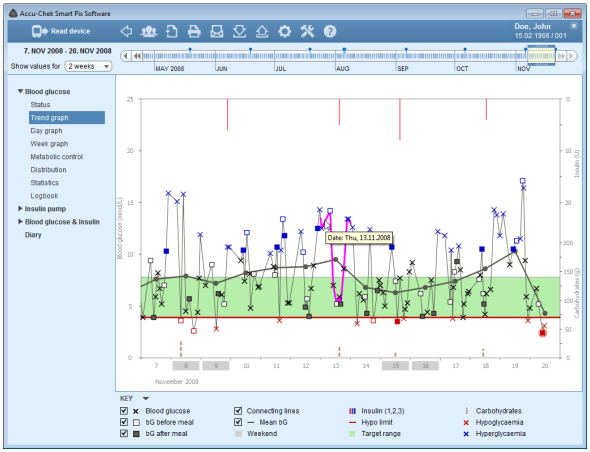
Displaying additional information in charts

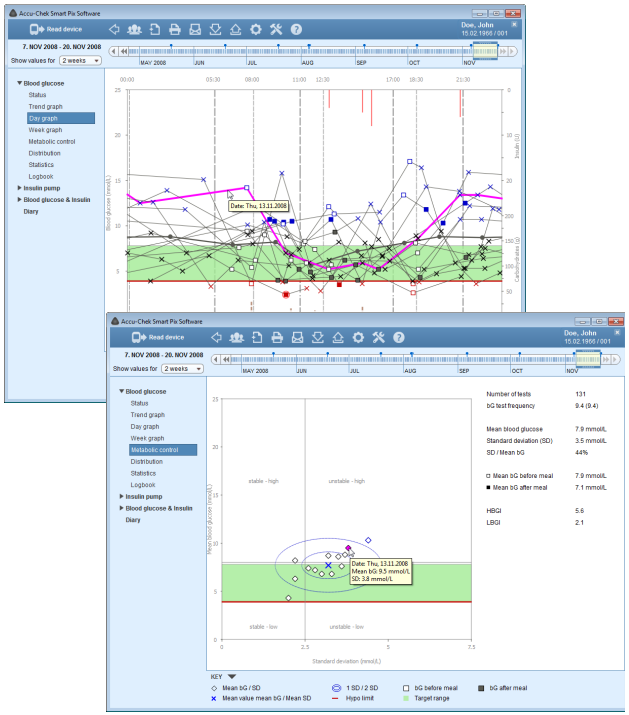
The *Trend graph*, *Day graph* and *Week graph* report elements allow you to display additional information for every entry.

- Move your mouse across the entry (blood glucose, insulin or carbohydrate amount, connecting line) you would like to have more information about.

Within a few seconds, a tooltip will be displayed showing you the details for this entry:

- For blood glucose: date, time, test result, flag (before/after meal, if applicable), comment.
- For insulin: date, time, amount of insulin, comment.
- For carbohydrates: date, time, amount, comment.



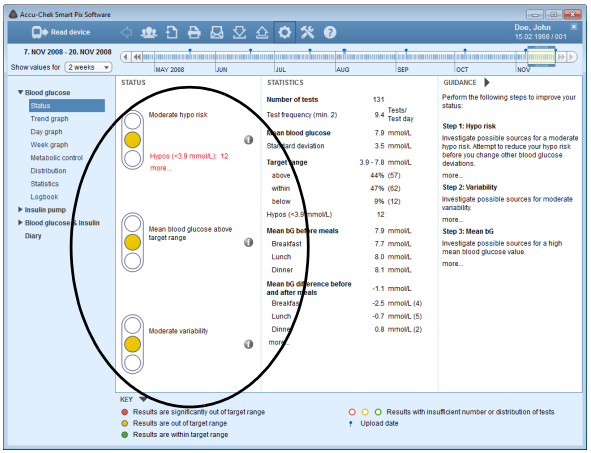


Selecting chart contents

The *Trend graph*, *Day graph*, *Week graph* and *Metabolic control* report elements allow you to select certain elements (thus highlighting them) for examination in this report or other reports.

- Simply clicking a connecting line or an entered test point marks the day's tests belonging together. If you keep the CTRL key pressed while clicking, you can mark additional days.
- Once you have marked a chart element, you can switch to another report; the highlighting will be visible in this report too.
- Double-clicking the highlighted element will directly open the tabular record; the respective day will be highlighted.
- To undo the highlighting, simply click an empty area in the chart.

5.3 Blood glucose: contents of the report



Status

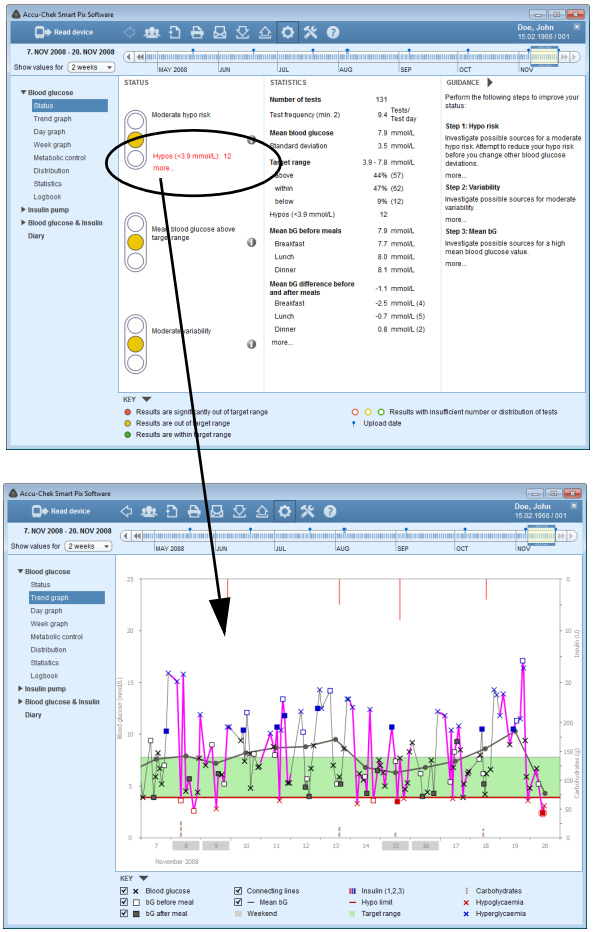
Status pane

The *Status* report element contains a summarised assessment of the read data in relation to the target range and the limits specified in the configuration. This report element helps to quickly gain an overview and does not contain any detailed information about individual results.

The *Status* report element will display an assessment of the data only if the number of tests and the distribution of tests throughout the day is sufficient (see page 37).

The *Status* pane on the left will give you a basic assessment of the read test results while considering the following three parameters:

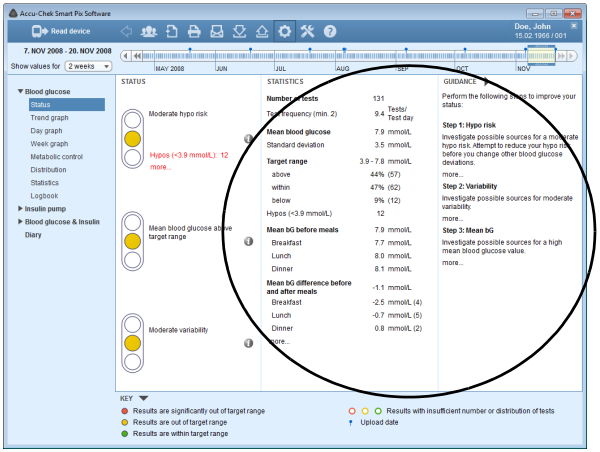
- Hypo risk
- Mean blood glucose
- Variability



For these three parameters, you will find the corresponding result specification, the set target value or target range, and also a symbolic traffic light indicating “Keep it up!”, “Watch out!” or “Stop!”.

- If the values fall inside the specified range, this is indicated by the colour **green**.
- If the values fall marginally outside the specified range, this is indicated by the colour **yellow**.
- If the values fall significantly outside the specified range, this is indicated by the colour **red**.

If information about hypoglycaemic situations is displayed in the *Hypo risk* area, you can click on *more...* in this note to go directly to the report element *Trend graph*. The days on which these hypoglycaemic situations occurred are already marked and can easily be examined in more detail.



Statistics pane

Here you will find the following statistical analyses on the available data:

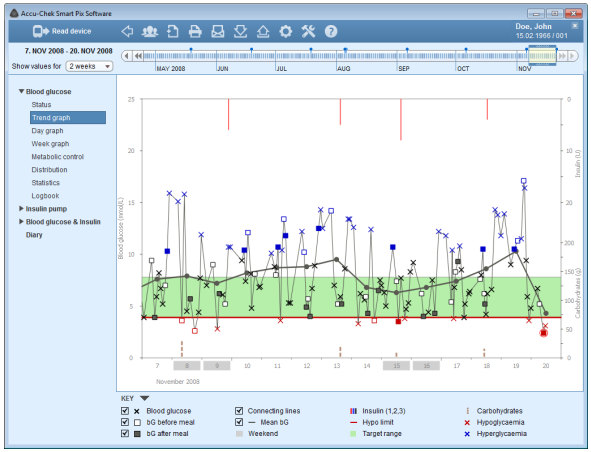
- Total number of analysed results
- Frequency of blood glucose tests (tests per day)
- Mean blood glucose
- Standard deviation (SD)
- Target range
- Number of values above the target range
- Number of values within the target range
- Number of values below the target range
- Number of hypos
- Mean blood glucose before meals (if available)
- Mean blood glucose before and after meals (if available)

As with all further reports, the results and statistics always refer to the set time range. If you click on *more...* in this area, you go directly to mealtime-related statistics of the *Logbook* report element.

Guidance pane

This pane gives you guidance regarding the results in the *Status* pane. These recommendations may be helpful for optimising the results.

Recommendations are displayed in a short version. Click *more…* to display the complete text of the recommendation.



Trend graph

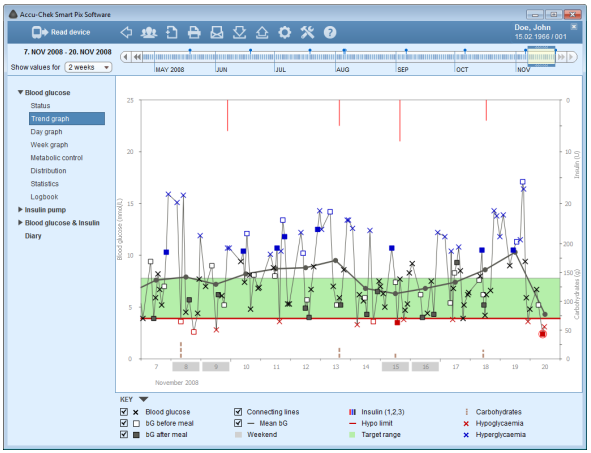
Detailed: This report element shows the trend for several test results over the selected time range. In this report element, you can display the following results:

- Blood glucose values
- Insulin amounts (bolus insulin only)
- Carbohydrate amounts

You will find the days, months and years along the horizontal (x) axis and the blood glucose values along the vertical (y) axis. For your guidance, the blood glucose values (represented by various icons) are connected by a line, provided the corresponding tests are no more than 10 hours apart. The various icons are explained briefly in the legend; for more details, please see page 70.

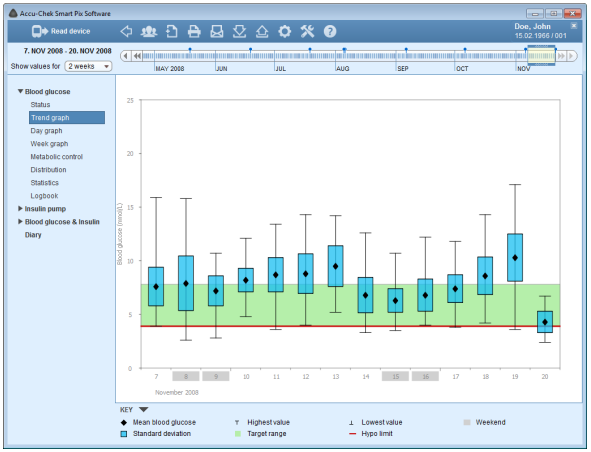
For further guidance, you can see the set target range in the background of the chart (as a green bar), the hypo limit (as a red line) and the hyper limit (if shown, as a blue line). Days that are usually non-work days (weekends) are additionally highlighted with a light blue on the horizontal axis.

In addition to the thin connecting line between the various blood glucose values, you will also see a (thicker) grey curve: the day-to-day trend of the mean blood glucose value.



Here you will also find a display of insulin amounts (if stored in the meter or entered in the record). Each insulin amount is plotted top down in the chart. You can see the associated amounts at the top of the right-hand y-axis.

At the bottom of the chart, you will see carbohydrate amounts (if stored in the meter or entered in the record). To facilitate evaluation of the amounts, the bars are represented by small separate blocks. Each complete block represents a certain carbohydrate amount in the set unit (e.g., 10 g, 1 BE); smaller blocks represent a certain fraction of these amounts (25, 50 or 75 %). At the bottom of the right-hand y-axis, you will find the scale for carbohydrate amounts.



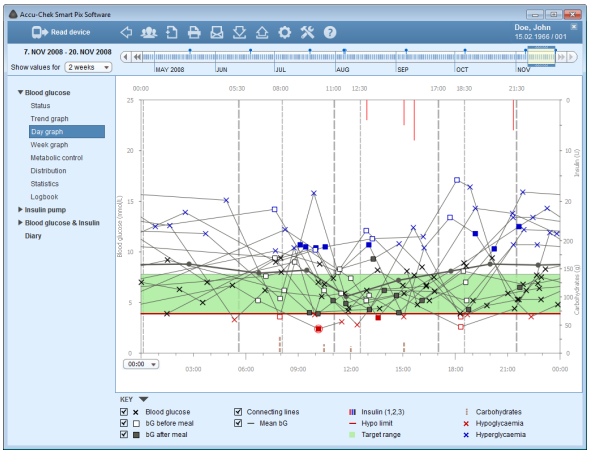
Trend: Here you will find the mean value for each individual day from the selected time range displayed as a single dot (black diamond) for the respective date. Standard deviation and highest and lowest values are plotted according to the icons described on page 72.

If you position the mouse cursor on a value bar, a tooltip will be displayed shortly thereafter, showing you the corresponding figures. These figures are:

- Number of analysed test results
- Highest, mean and lowest value of the analysed results
- Standard deviation or variance of the analysed results

Day graph

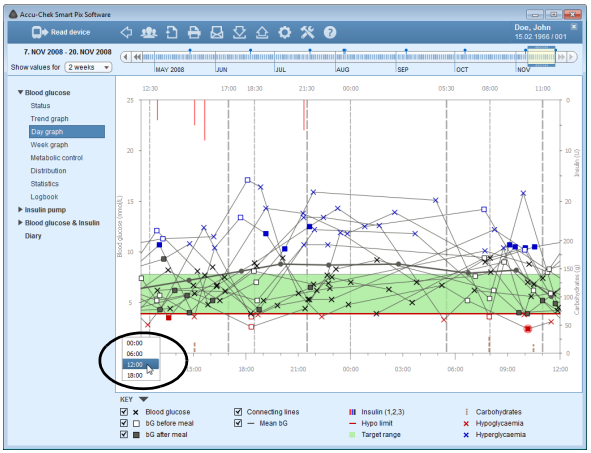
This report element is used to facilitate recognition of patterns recurring on a daily basis. For this purpose, all the data is positioned in a 24-hour grid. As a result, all the tests performed at a specific time of day are shown at the same position on the time axis. If the meal segments are defined in the meter, the information will be analysed when the time axis is set out. If they are not, the meal segment settings of the configuration will be used. The report element can be represented in two different styles. The one appearing on your report is defined during configuration. In a second tab you will also find a tabular representation as a *Logbook* (see page 95).



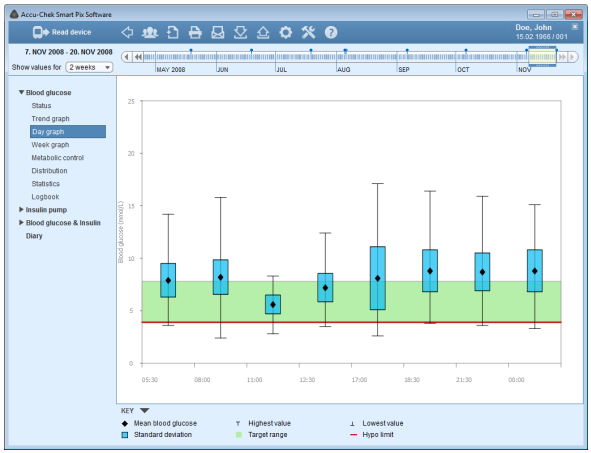
Detailed: All the blood glucose values are plotted at the relevant time of day according to the time when the test was performed. Results which are no more than 10 hours apart are connected by lines in chronological order for a better overview. A (thicker) grey curve represents the trend of the mean value for every meal segment. Meal segment boundaries are represented by vertical grey lines. Beginning and end of the meal segments are indicated above the chart.

Here you will also find a display of insulin amounts (if stored in the meter or entered in the record). Each insulin dose is plotted top down in the chart and you can see the associated amounts at the top of the right-hand y-axis.

At the bottom of the chart, you will see carbohydrate amounts (if stored in the meter or entered in the record). At the bottom of the right-hand y-axis, you will find the scale for the carbohydrate amounts.



You can shift the time axis, which normally runs from 0:00 to 0:00 (midnight), in 6-hour steps. This facilitates examination of the results obtained, e.g. at night.



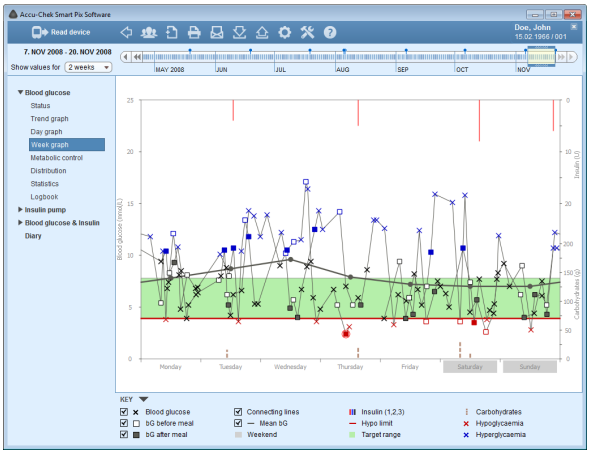
Trend: All the blood glucose values are assigned to one of eight meal segments according to the time when the test was performed. This creates eight areas displaying the mean blood glucose value (black diamond), standard deviation (blue bar) as well as the lowest and highest result.

If you position the mouse cursor on a value bar, a tooltip will be displayed shortly thereafter, showing you the corresponding figures. These figures are:

- Number of analysed test results
- Highest, mean and lowest value of the analysed results
- Standard deviation or variance of the analysed results

Week graph

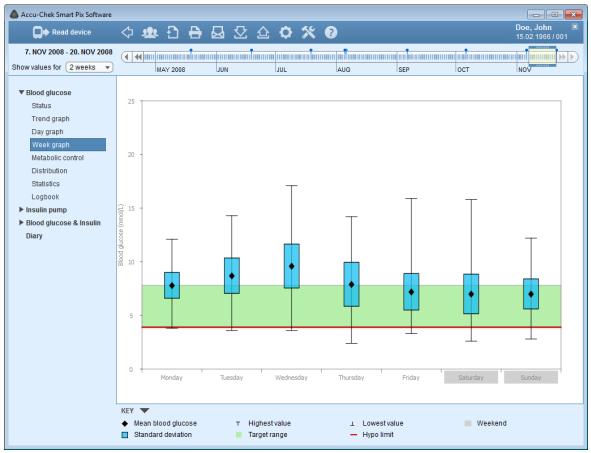
This report element is also used to facilitate recognition of recurring patterns, but here the reference point is the day of the week. It allows you to recognise changes in your metabolism which occur repeatedly on specific days of the week (e.g., exercise days). The report element can be represented in two different styles.



Detailed: All the blood glucose values are plotted on the chart according to the time when the test was performed and the respective day of the week. Results which are no more than 10 hours apart are connected by lines in chronological order for a better overview. The connecting lines are also drawn beyond individual weeks (if applicable). A (thicker) grey curve represents the trend of the mean value on the different days of the week.

Here you will also find a display of insulin amounts (if stored in the meter or entered in the record). Each insulin dose is plotted top down in the chart and you can see the associated amounts at the top of the right-hand y-axis.

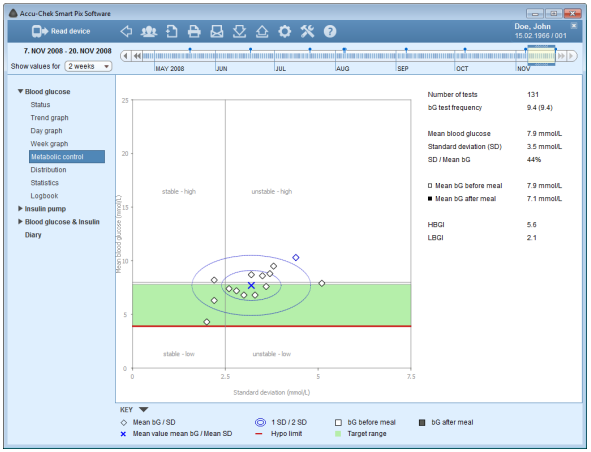
At the bottom of the chart, you will see carbohydrate amounts (if stored in the meter or entered in the record). At the bottom of the right-hand y-axis, you will find the scale for the carbohydrate amounts.



Trend: All the blood glucose values are assigned by date to one of the seven days of the week. Accordingly, you will see seven blocks indicating the mean blood glucose value (black box with a cross line), standard deviation (blue bar), and lowest or highest result of the respective day of the week.

If you position the mouse cursor on a value bar, a tooltip will be displayed shortly thereafter, showing you the corresponding figures. These figures are:

- Number of analysed test results
- Highest, mean and lowest value of the analysed results
- Standard deviation or variance of the analysed results



Metabolic control

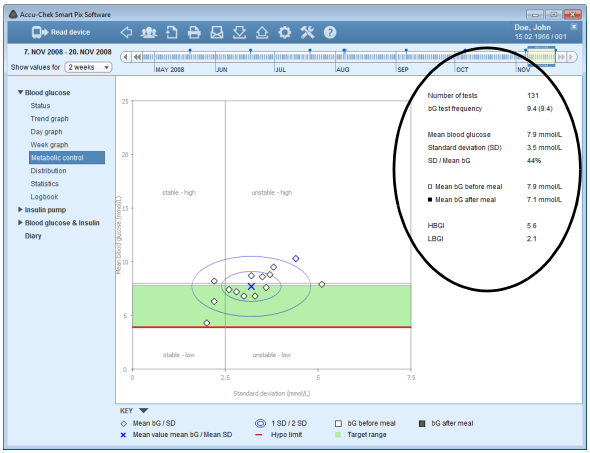
For each day of the analysed time range, its mean blood glucose value and standard deviation (SD/variance of the values) are calculated. These two results together provide the coordinates for making an entry (per day) in the chart. The mean blood glucose value is plotted along the y-axis while the standard deviation is plotted along the x-axis.

This type of presentation produces a “scatter plot”. To facilitate faster assessment of your metabolic state from this overview, the chart is split up into four “quadrants”. Each of these quadrants represents a certain metabolic constitution and is described by the attributes “stable/unstable” (referring to standard deviation) and “low/high” (referring to mean bloodglucose values). This gives each quadrant two attributes.

Example:
Mean blood glucose values below 8.3 mmol/L (or 150 mg/dL) with a standard deviation of less than 2.8 mmol/L (or 50 mg/dL) are plotted in the bottom left quadrant. Its attributes are “stable-low”. If both values are above these limits, the entry is made in the top right-hand quadrant (“unstable-high”).

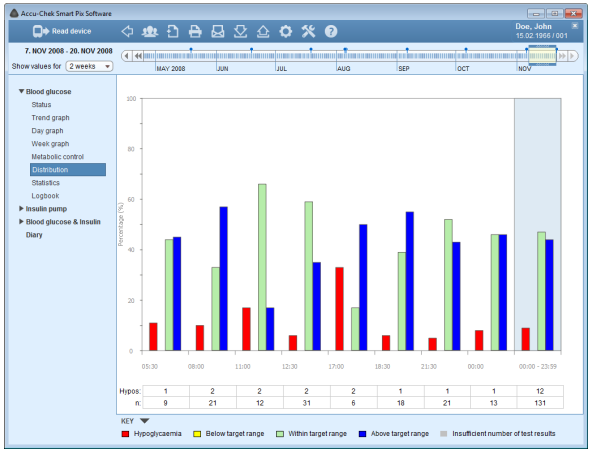
Two ellipses are plotted, centred around the mean value of all represented levels (marked by a blue cross). They illustrate the variance of the daily mean values and the daily blood glucose variability over the selected time range as a simple (1 SD) and two-fold (2 SD) standard deviation of the displayed values.

Good metabolic control can be recognised by the fact that there are as many dots as possible in the “stable-low” quadrant (bottom left) while there are no cases of hypoglycaemia, or as few as possible, in the respective time range.



In addition to the graphical display, you will find statistical information about the results included in the analysis. These are:

- **Number of tests:** Number of analysed blood glucose results in the selected time range.
- **bG test frequency:** Average number of blood glucose tests per day for **each day** of the analysed time range. In addition, the value **of only those days** when a test was performed at least once, is also displayed (in brackets).
- **Mean blood glucose:** Mean value of all analysed results.
- **Standard deviation (SD):** Standard deviation or variance of the analysed results.
- **SD / Mean bG:** This value indicates the variability of the blood glucose values with reference to the mean value. If the mean value is in the desired range, a ratio of less than 50 % (or better: 30 %) indicates a desirably low variability and thus good metabolic control.
- **Mean bG before/after meal:** Mean value from all results which have been obtained before or after meals and have been marked in the meter accordingly. Values are displayed only when appropriate information is stored in the meter.
- **HBGI / LBGI:** These figures represent the frequency and the resulting risk of blood glucose values being too high or too low (see bibliography on page 126). Figures should be as low as possible.

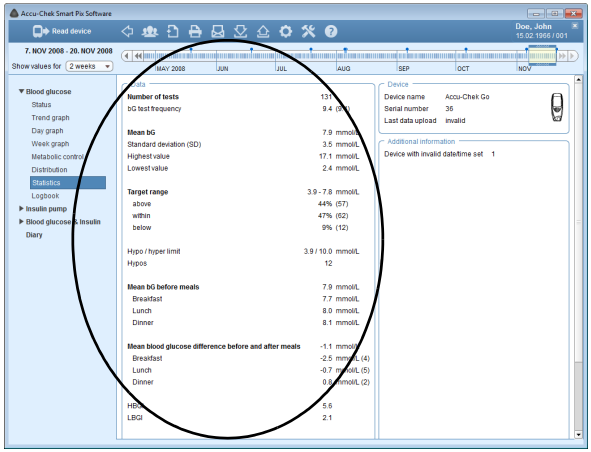


Distribution

For each meal segment, you will find a bar chart here representing the percentages of values above, within and below the target range. The eight consecutive meal segments are arranged next to each other. If there are less than 5 test results for a meal segment, the bar is displayed in grey. The right part of the bar chart (blue background) shows a summary of the corresponding information for the whole day.

Below the bar chart, you can see the number of hypoglycaemic situations (*Hypos*) that occurred for each meal segment along with the number (*n*) of test results obtained and analysed for the respective meal segment.

If the meal segments are defined in the meter, the information from the meter will be used. If they are not, the meal segment settings in the Accu-Chek Smart Pix software configuration are used.



Statistics

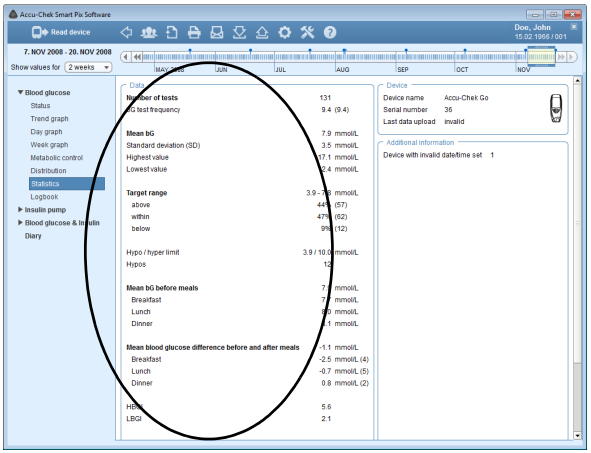
The *Statistics* report element contains general and statistical information about the values processed for the selected time range. Here you will find the following information:

Time range

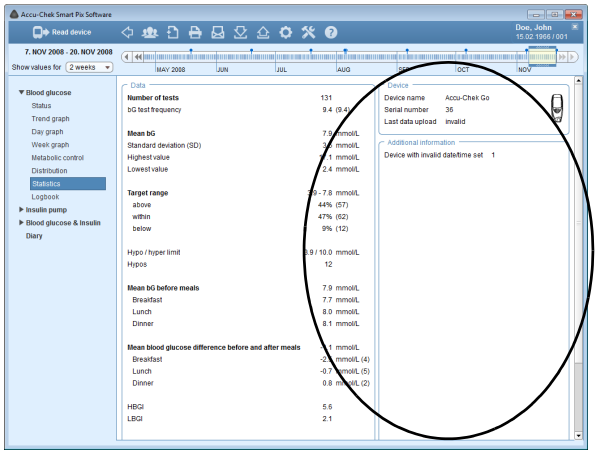
- Time range considered in the report, with start and end date.

Report

- **Number of tests:** Number of analysed blood glucose results in the selected time range.
- **Highest value/Mean bG/Lowest value:** Highest and lowest blood glucose value tested in the selected time range, and the average of all the values tested.
- **Standard deviation (SD):** Standard deviation or variance of the analysed results.
- **bG test frequency:** Average number of blood glucose tests per day for **each day** of the analysed time range. In addition, the value **of only those days** when a test was performed at least once, is also displayed (in brackets).
- **Target range:** The target range used for the report.



- **Hypo / hyper limit:** Blood glucose values below the hypo limit are marked as a hypoglycaemia; results above the hyper limit are marked as a hyperglycaemia.
- **Above/Within/Below target range:** Percentage of test results above, within or below the target range (in percent).
- **Hypos:** Number of hypos.
- **Mean bG before/after meal:** Mean blood glucose value before and after meals (if available) and the difference between these results.
- **HBGI / LBGI:** These figures represent the frequency and the resulting risk of blood glucose values being too high or too low (see bibliography on page 126). Figures should be as low as possible.
- **HI / LO / control results:** Number of test results above (HI) and below (LO) the measuring range and number of tests with control solution.



Device

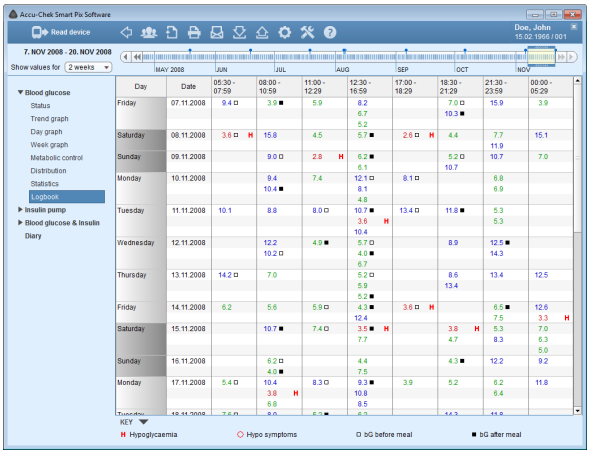
- **Device name**
- **Serial number:** Serial number of the meter.
- **Last data upload:** Date and time of the last data upload, including the time settings difference between device and computer (if exceeding 5 minutes).
- **Meter** (icon): Displays the meter used.

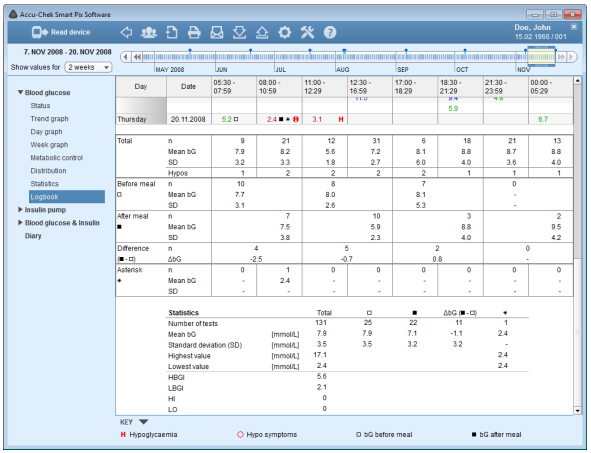
If you used several meters in the selected time range, this information is given for each meter.

Additional information

This information is only displayed if required:

- **Results without date/time:** Number of test results which were stored without date and time information.
- **Results with warnings:** Number of test results which were stored with temperature warning, expiry note, etc.





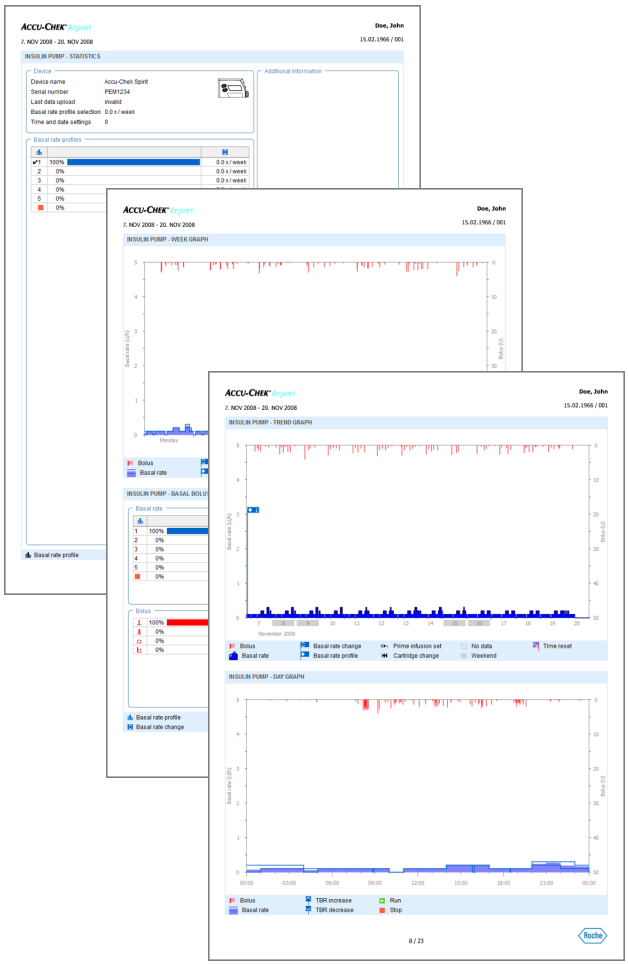
Logbook

The logbook creates a tabular overview of blood glucose test results. The table of values (sorted by date and meal segments) is created according to the date and time information of the blood glucose results. Values without any date or time information will not be displayed in the logbook. They are, however, contained in the *Diary* report element.

If the meter transfers the *Before meal* ☐ or *After meal* ■ information related to the test results, an enhanced statistical analysis will be displayed at the bottom. The defined eight meal segments are summarised into four groups, each containing one meal plus the period before and after the meal. Mean values and standard deviations are calculated separately (before/after meal) for each of these groups. For paired values, the average change of the blood glucose result is also calculated. Such a paired value results from performing a first test before ☐ and a second test after ■ the meal, with the second test occurring within one or two hours after the first test.

If the analysed time range contains blood glucose values which are marked as a *User-defined* event, separate statistics are calculated and displayed for these.

5.4 Insulin pump: general information about the reports



Types of reports

The Accu-Chek Smart Pix software creates single-page or multi-page reports for defined periods (e.g., the last 2 or 4 weeks). The time range can be selected as needed (as with blood glucose). A(n) (insulin pump) report can always contain any of the following report elements:

[1] Trend graph
[2] Day graph
[3] Week graph
[4] Basal rates
[5] Basal bolus
[6] Statistics
[7] Lists

The illustration on the left shows examples of the printed version of the report.

Graphical elements of the reports

In all reports, you will find legends explaining the meaning of individual elements. In the following, you will find detailed explanations of the various elements.

Icons On the insulin pump reports, you will find the following icons:

Basal rate (represented in the *Trend graph*)

Average total basal insulin per day

Basal rate profile

Basal rate change

Basal rate change (with name; represented in the *Trend graph*)

Temporary increase in basal rate

Temporary decrease in basal rate

Active basal rate profile (*Statistics*)

Switch to a named basal rate profile (e.g., “1”)

Switch from a named basal rate profile (e.g., “1”) to another named basal rate profile (e.g., “2”)

Total of basal insulin + bolus insulin per day

Standard bolus, represented in charts top down

Scroll bolus, represented in charts top down

Extended bolus, represented in charts top down; the width of the bar shows the duration of the bolus delivery

Multiwave bolus, represented in charts top down; the width of the bar shows the duration of the extended portion

Bolus advice, always appears in combination with one of the four bolus type icons described above. These boluses have been calculated with a bolus calculator (from a corresponding meter). Bolus advice is only displayed if the bolus was delivered and is thus stored in the pump.

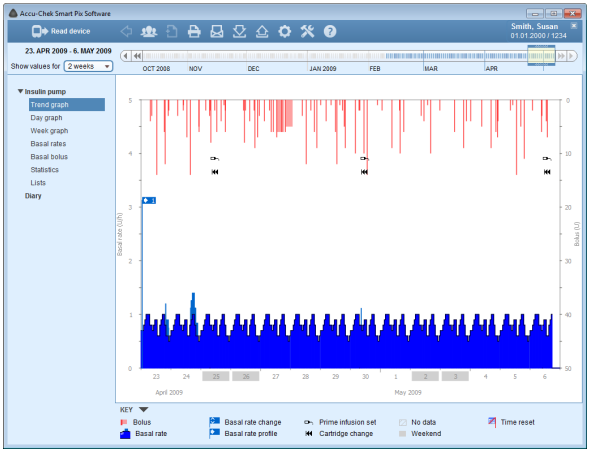
Prime infusion set

Return of piston rod (cartridge change)

Insulin pump run

Insulin pump stop

5.5 Insulin pump: contents of the report



Trend graph

This report element shows the trend in insulin dosage over the selected time range. You will find the days and months along the horizontal (x) axis and the respective amounts of insulin delivered along the vertical (y) axis.

The basal rate chart is at the bottom, and the individual boluses are shown at the top. Therefore, you will find the basal rate scale along the left-hand y-axis (bottom up) and the scale for the boluses along the right-hand y-axis (top down).

Various events are also displayed in addition to the insulin dose. These are:

- Pump events
- Switch of the basal rate profile
- Changes in basal rate

The various icons are explained briefly in the legend; for more details, please see page 97.

As in the blood glucose report elements, the non-work days (the default is set to weekends) are additionally marked with a light blue bar on the horizontal axis.

Day graph

This report element is used (as with blood glucose) to facilitate recognition or illustration of patterns recurring on a daily basis. For this purpose, all data is placed on a 24-hour grid. This allows you to easily recognise frequent manual basal rate changes at certain times, e.g., to facilitate general adjustment of the basal rate.

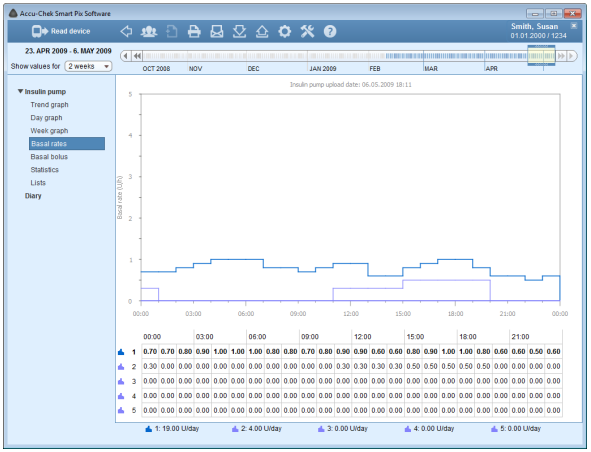
The mean basal rate is displayed as an area coloured in blue; the maximum and minimum basal rate at the respective time of day is shown as a thin blue line.

In this chart, you will not only find basal rates and boluses but also information about the start and stop of the insulin pump and about a temporary decrease or increase in the basal rate.

Week graph

This report element is also used (as with the Day graph) to facilitate recognition of recurring patterns (e.g., repeated basal rate changes), but here the reference point is the day of the week.

In this chart, you will not only find basal rates and boluses but also information about basal rate changes and the selection of basal rate profiles.



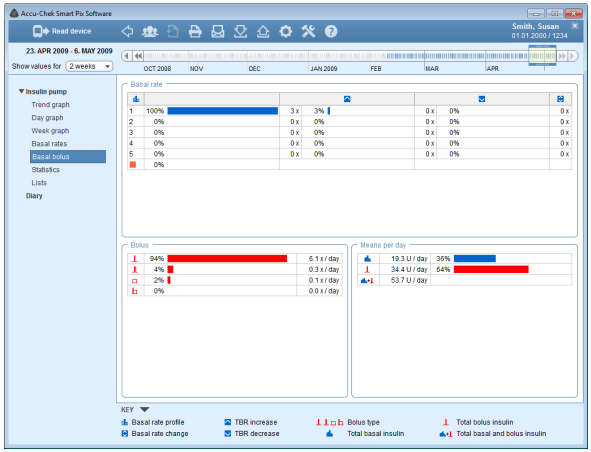
Basal rates

This report element displays the basal rates set in the insulin pump at the time of data transfer in order to facilitate comparison. The currently active basal rate profile can be identified by the thicker dark blue line. The total daily amounts of the respective profiles are indicated in the legend, and the active basal rate profile is highlighted in colour.

A tabular representation of the basal rates is displayed below the chart.

The table view contains the specified amount of insulin per hour as a numeric value in a 24-hour grid. All basal rate profiles are displayed one below the other. The active basal rate profile is displayed in bold.

This report element is only displayed if data was read from the pump in the selected time range. The upload date (at which the profiles were active) is specified in the heading (e.g., “Basal rates Aug. 31, 2013”). If no data was read from the pump in the selected time range, this report element will **not** be displayed.



Basal bolus

The tabular *Basal bolus* report element shows the (absolute and relative) frequency with which, e.g., a certain basal rate profile or bolus type was used.

Basal rate

Here you can see, for example, how often the basal rate of a certain basal rate profile was temporarily increased or decreased and how long (as a percentage) it remained in this changed state. If there are frequent changes and/or if manually changed basal rates are used for a long time, you may need to make general adjustments.

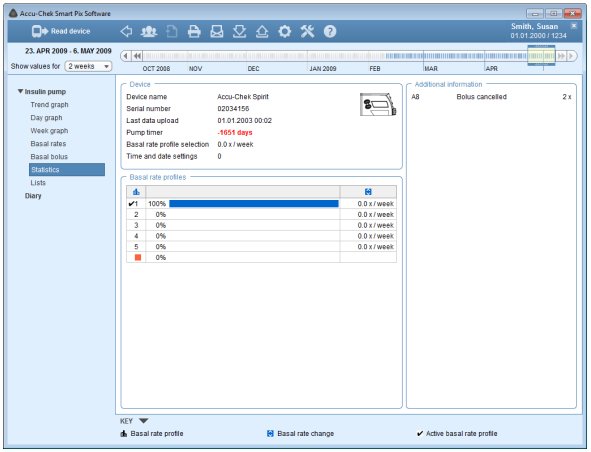
The number of times the basal rate has been reprogrammed is displayed in the last column. For the sake of completeness, the *Basal rate* table also includes the times when the insulin pump was in STOP mode.

Bolus

This table shows both the (relative) frequency of use with regard to certain types of bolus and their average number per day. The proportion of boluses which were delivered using bolus advice is represented in a different colour (orange).

Means per day

Here you will find the average values for basal and bolus insulin as well as their percentage of the total amount.



Statistics

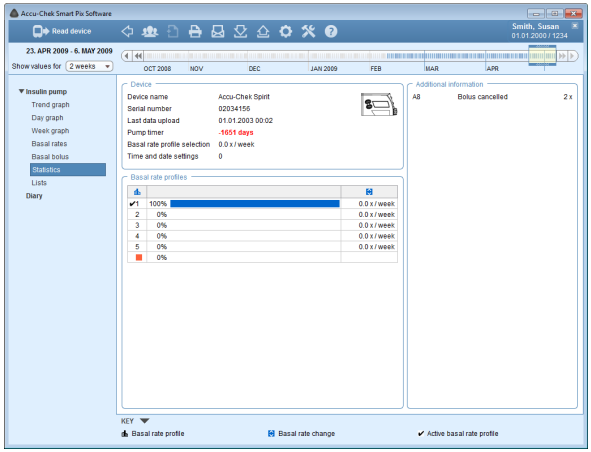
The *Statistics* report element contains general and statistical information about the imported values. Here you will find the following information:

Time range

- Time range considered in the report, with start and end date.

Device

- **Insulin pump** (icon): Displays the insulin pump used.
- **Serial number:** Serial number of the insulin pump.
- **Last data upload:** Date and time of the last data upload, including (if applicable) the time settings difference between device and computer.
- **Pump timer:** Remaining time of use for this insulin pump (Accu-Chek Spirit Combo insulin pump: This setting is country-specific and may not be visible on your pump).
- **Basal rate profile selection:** How frequently (per week) was the insulin pump switched to a different basal rate profile.
- **Time and date settings:** How often was the time and date information updated (e.g., due to daylight saving time, transcontinental flights, etc.).



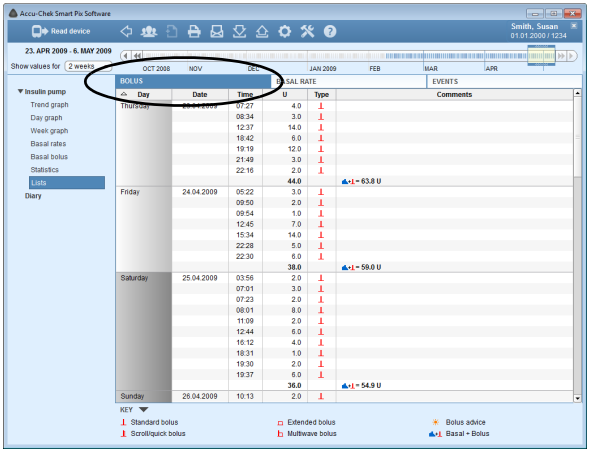
Basal rate profiles

The table shows the percentage of certain basal rate profiles (plus times when the insulin pump was in STOP mode). The currently active basal rate profile has a check mark ✔.

Additional information

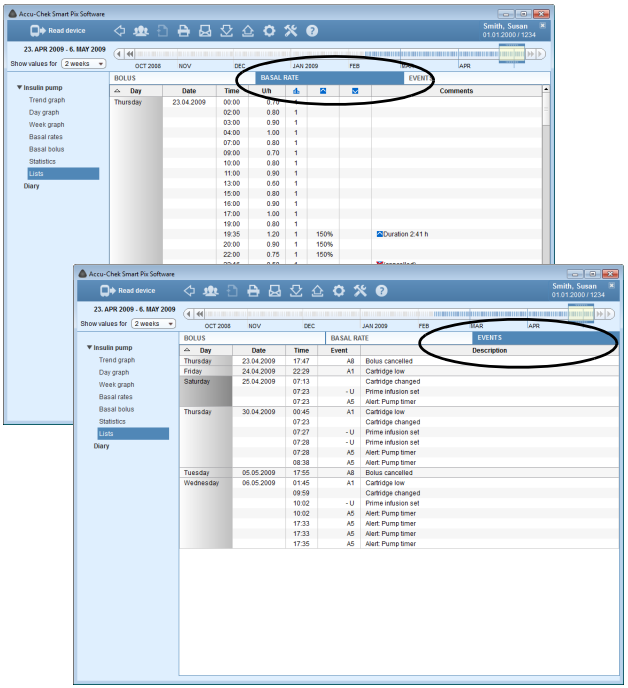
This information contains error messages and warnings (and their number) which were stored in the insulin pump.

Lists



The three groups of information, *Bolus*, *Basal rate* and *Events*, are also output as lists (on three separate tabs). You can specify whether these tables are to be sorted in ascending or descending order by clicking the table heading (e.g., *Day*, *Date*). In these lists, you will find detailed documentation of each individual event stored in the insulin pump, including date and time. Boluses which were delivered using bolus advice are marked with the corresponding ☀ icon.

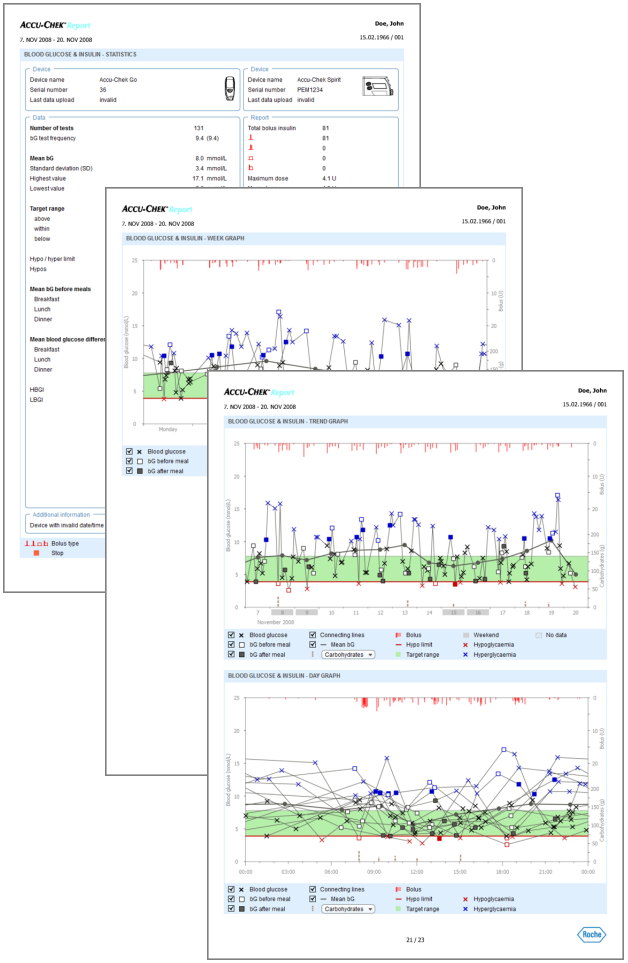
To display a list, click the corresponding tab.



5.6 Blood glucose and insulin pump: combined report

If you analyse data from a blood glucose meter together with data from an insulin pump, combined report elements of the simultaneously obtained information can provide useful indications for treatment. In addition to the individual blood glucose and insulin pump reports, a combined report is therefore available.

If you want to analyse the data of several devices together, the devices must be **synchronised**, i.e., all devices involved should have the same date and time settings. Otherwise the sequence of stored events may be interpreted incorrectly.



Types of reports

The Accu-Chek Smart Pix software creates single-page or multi-page reports for defined periods (e.g., the last 2 or 4 weeks). The time range of the combined report is the time range set for blood glucose or insulin pump reports. The blood glucose values are always displayed in the *Detailed* style, irrespective of the selected setting for the individual blood glucose report. A combined report can always contain any of the following report elements:

[1] Trend graph

[2] Day graph

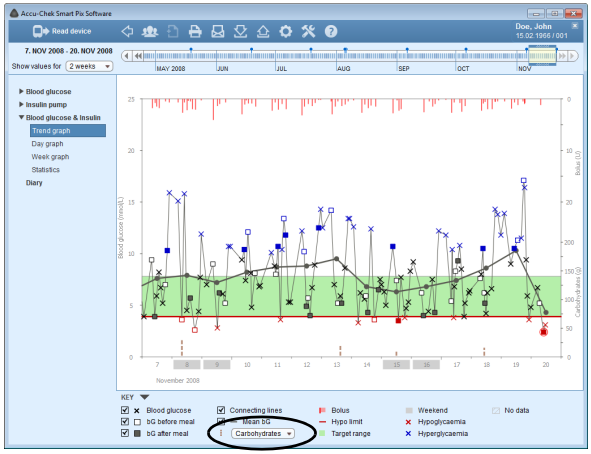
[3] Week graph

[4] Statistics

The illustration on the left shows examples of the printed version of the report.

Graphical elements of the reports

In all reports, you will find legends explaining the meaning of individual elements. For detailed explanations of the various elements, see the preceding descriptions of the blood glucose and insulin pump reports on page 70 and page 97.



Trend graph

This report element shows you the trend in test results and insulin pump data over the selected time range. You will find the days and months along the horizontal (x) axis and the blood glucose values can be seen on the vertical (y) axis. In addition, delivered bolus insulin amounts are plotted in the chart (top down) and selectively either the basal rate or carbohydrates (bottom up) is displayed in the chart. The associated values can be seen on the right-hand y-axis.

Bottom up (selected in the legend):

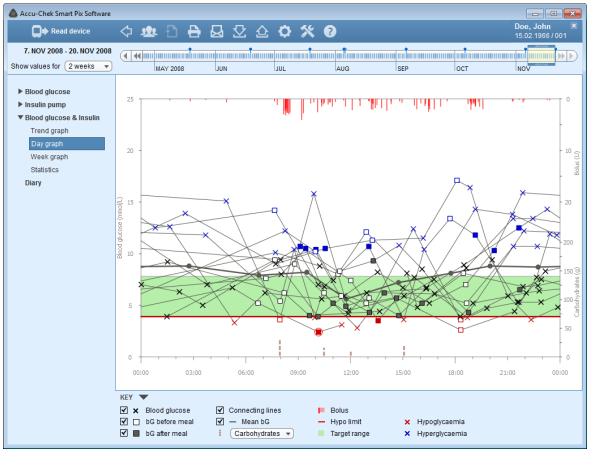
- blue = basal rate **or**
- brown = carbohydrates

Top down:

- red = bolus

For a better overview, this representation does not display pump events. If required, you can find this information in the individual reports.

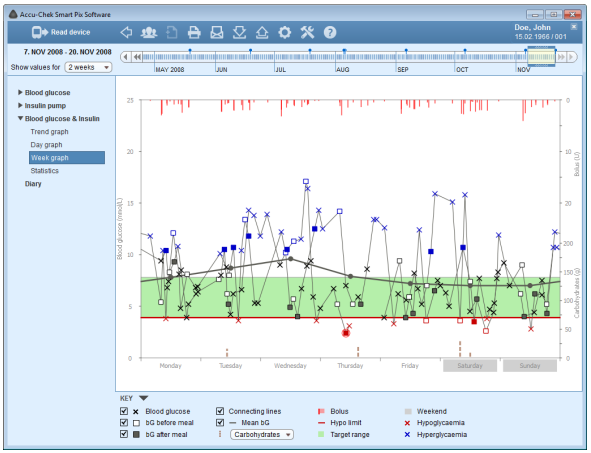
Day graph



As with the individual reports, this view facilitates recognition of patterns recurring on a daily basis. Here, too, all data is placed in a 24-hour-grid, making it easier to see the connection between insulin doses (bolus and basal insulin) and measured blood glucose values in relation to the time of day. All the information is plotted at the relevant time of day according to the time when the test was performed.

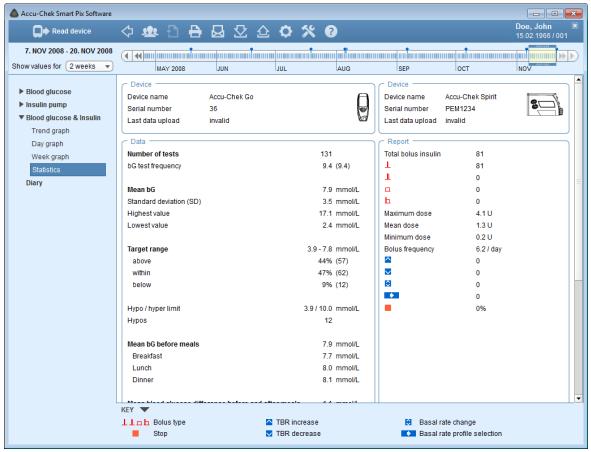
The elements and setup options used in the display correspond to those in the *Trend graph*.

Week graph



This report element is also used to facilitate recognition of recurring patterns, but here the reference point is the day of the week. All the information is plotted on the chart according to the time the test was performed and the respective day of the week.

The elements and setup options used in the display correspond to those in the *Trend graph*.



Statistics

The *Statistics* report element contains general and statistical information about the values processed for the selected time range. Here you will find the following information:

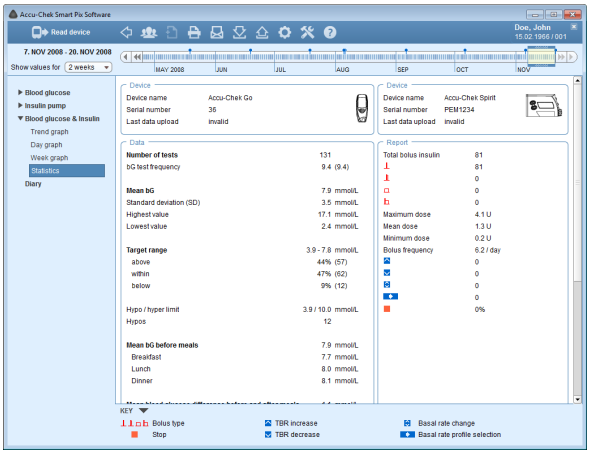
Time range

- Time range considered in the report, with start and end date.

Device

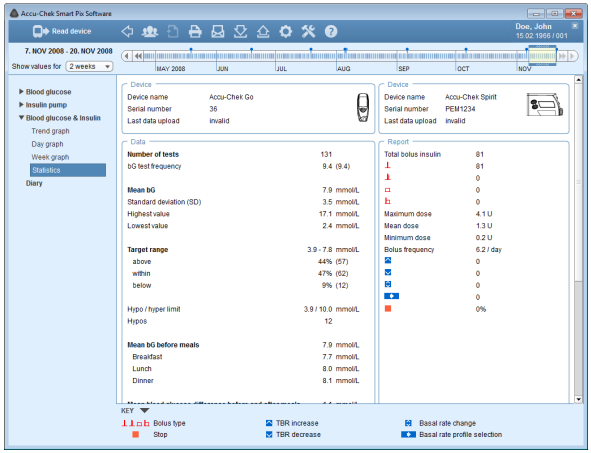
- **Device name**
- **Serial number:** Serial number of the meter/insulin pump.
- **Last data upload:** Date and time of the last data upload, including (if applicable) the time settings difference between device and computer.
- **Device** (icon): Displays the device used in the selected time range.

If you used several meters in the selected time range, this information is given for each meter.



Data

- **Number of tests:** Number of analysed blood glucose results in the selected time range.
- **Highest value/Mean bG/Lowest value:** Highest and lowest blood glucose value tested in the selected time range, and the average of all the values tested.
- **Standard deviation (SD):** Standard deviation or variance of the analysed results.
- **bG test frequency:** Average number of blood glucose tests per day for **each day** of the analysed time range. In addition, the value **of only those days** when a test was performed at least once, is also displayed (in brackets).
- **Target range:** The target range used for the report.
- **Hypo / hyper limit:** Blood glucose values below the hypo limit are marked as a hypoglycaemia; results above the hyper limit are marked as a hyperglycaemia.
- **Above/Within/Below target range:** Percent and (in brackets) amount of test results above, within and below the target range.
- **Hypos:** Number of hypos.
- **Mean bG before/after meal:** Mean bG value before and after means (if available) and the difference between these values.



- **HBGI / LBGI:** These figures represent the frequency and the resulting risk of blood glucose values being too low or too high (see bibliography on page 126). Figures should be as low as possible.
- **HI / LO / control results:** Number of test results above (HI) and below (LO) the measuring range and number of tests with control solution.

Report

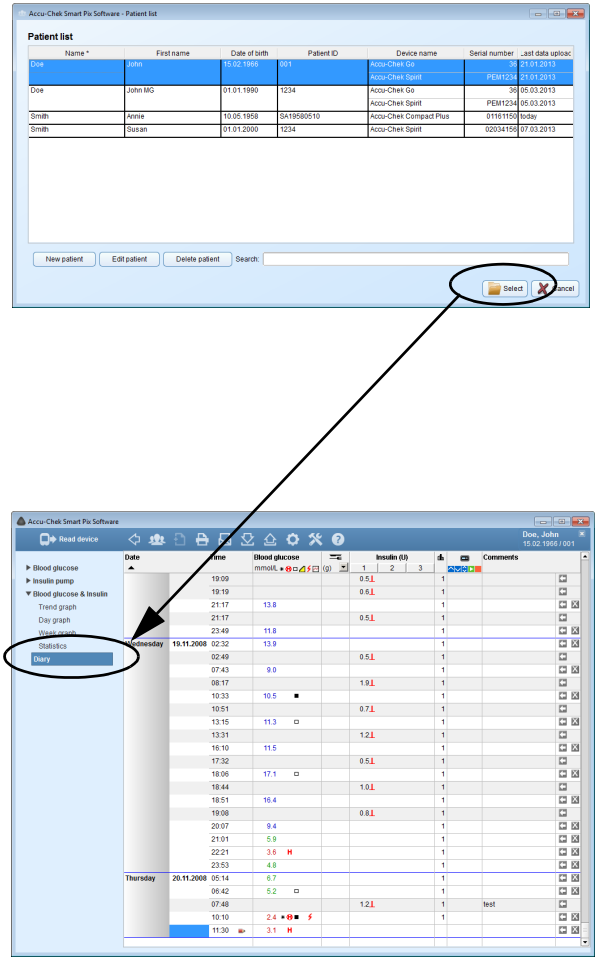
- **Total bolus insulin:** Number of respective bolus deliveries, according to bolus type.
- **Maximum/Mean/Minimum dose:** Highest and lowest single insulin dose delivered in the selected period and the average of all insulin amounts delivered.
- **Bolus frequency:** Average frequency of insulin amount delivery per day (combined without considering the bolus type).
- **Basal rate change:** Number of manual increases and decreases of the basal rate as well as the number of changes to and switches of the basal rate profile.

Additional information

This information is only displayed if required:

- **Results without date/time:** Number of test results which were stored without date and time information.
- **Results with warnings:** Number of test results which were stored with temperature warning, expiry note, etc.

5.7 List (Record)



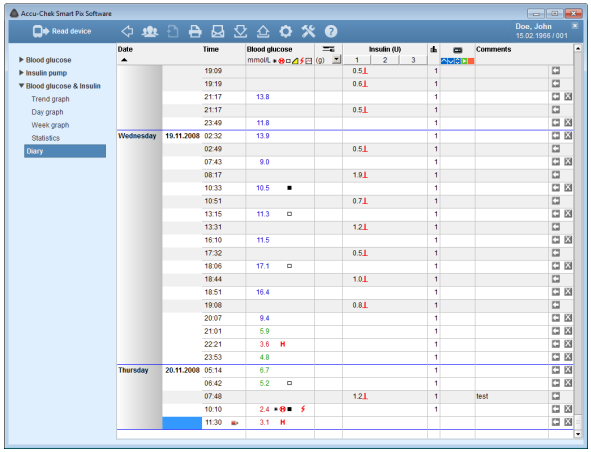
The term “record” describes the personal data saved which is read from devices primarily during imports. This data is the raw material used to create reports. You can view and edit this data as a report in the analysis view, or as a tabular *Diary*.

When opening a saved record, the associated report will be created and displayed at the same time. When adding entries to the record or editing existing entries, these changes will also apply to the relevant report elements.

- You can create and save any number of records.
- You can automatically add data read from devices to its assigned record.
- You can add your own plain-text comments and additional information to every record entry.

Every record assigned to a patient is saved automatically when you leave the record view or close the Accu-Chek Smart Pix software. Records that were not saved or assigned will, however, be deleted after the import.

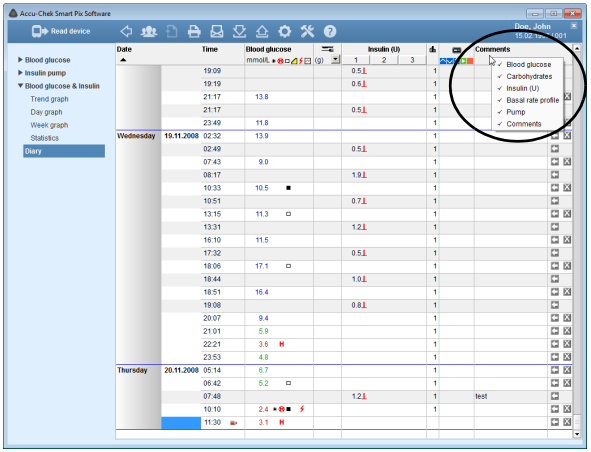
Please see chapter 4 for descriptions about creating, opening and managing records. The following descriptions will explain the functions and editing options in an opened record.



Contents of the record

The record displays as a tabular list of sorted blood glucose results, insulin pump data and further information. The table of values (sorted by date and meal segments) is created according to the date and time information of the blood glucose results and pump data. You can specify whether this table is to be sorted in ascending or descending order by clicking the table heading (e.g., *Date*). This table will always display all existing data, irrespective of the time range settings in the report.

Adjusting the list view



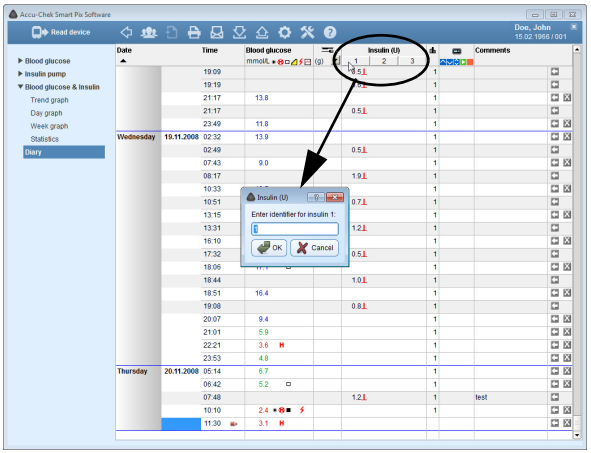
You have the following options for customising the table to suit your personal requirements:

Column hide option

- Right-click the table header to open the context menu.
- All the columns currently selected are ticked. Click the name of the column you wish to hide.
- The check mark in front of the column name is removed and the column is now hidden.

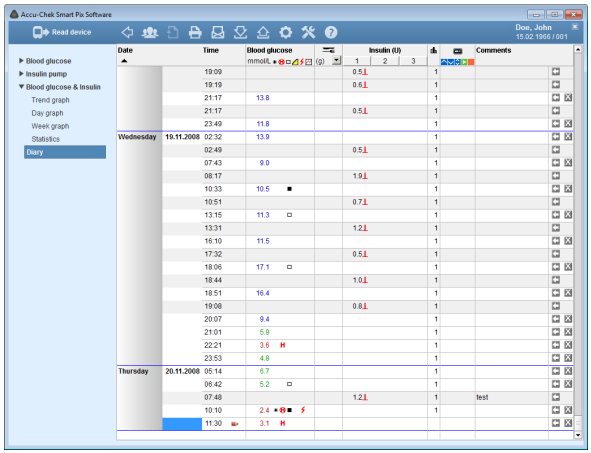
By clicking the name again you can re-display the hidden columns.

Naming insulins



Insulins are listed with the names *1*, *2*, and *3* (see page 123). Instead of the column headings *1, 2, 3* you can also enter abbreviations (up to 5 characters, e.g., “NPH” or “Mix”) for each type of insulin.

- Click the respective figure in the column heading.
- Enter the desired name (up to 5 characters).
- Click the *OK* button to save the changes and to close the dialog box.



Editing list entries

"List entry" always refers to a complete table row divided into various information sections (e.g., *Blood glucose* or *Comments*). Each list entry has at least a date and a time.

You have the following options for editing list entries:

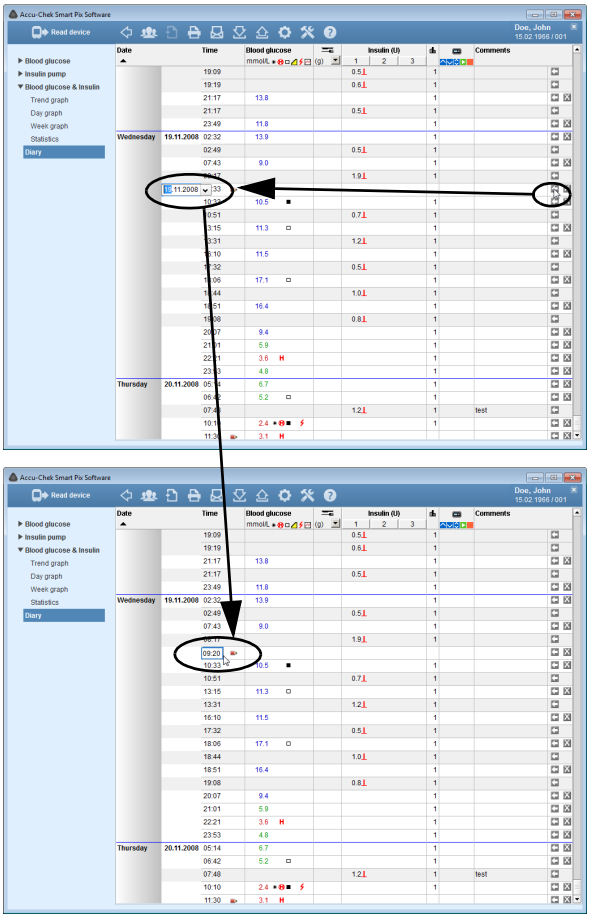
You can:

- add extra information to existing list entries.
- manually add new entries and manually add test results to these entries. Data entered manually can also be changed later.
- flag existing entries as invalid (e.g., incorrect measurements) to exclude them from the reports.

You cannot:

- modify date or time information or test results read from meters.
- mark as deactivated or modify any entries read from insulin pumps.

An open record is automatically saved as soon as you close it.



Adding or deactivating list entries

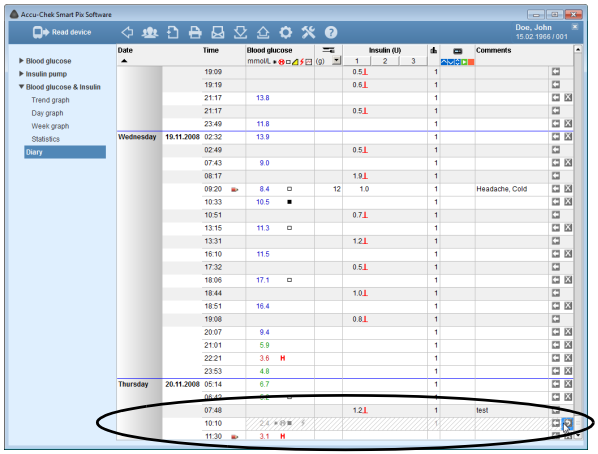
On the right-hand side of every list entry there are one or two small buttons with the following functions:

- With the button you can add a row **above** the present row.
- With the button you can delete the highlighted entry (e.g., to exclude incorrect measurements from reports and statistics). This button is only displayed for entries which can be deactivated.

To add a list entry:

- Double-click the button in the row above which you wish to create an entry.
- Set the desired date and time for the entry using the arrow buttons.

If the date and time setting does not match the current position of the entry, the row will automatically move to the right position.



To deactivate a list entry:

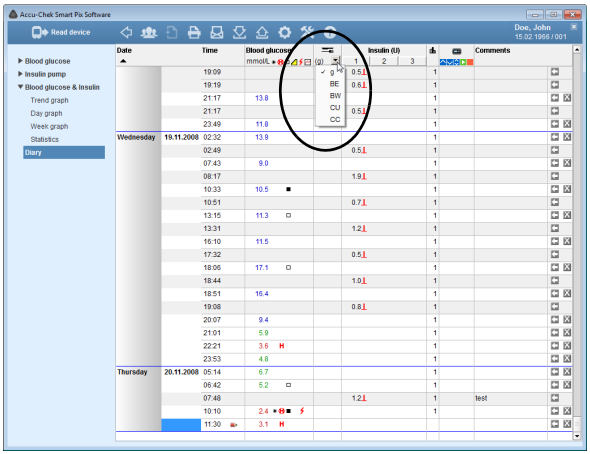
- Double-click the button in the row you wish to deactivate. The row will now be displayed shaded in grey.

This list entry will no longer be included in reports and statistics.

To reactivate a deactivated list entry:

- Double-click the button in the row you previously deactivated.

You can also use the context menu to add or deactivate entries. To do so, right-click an entry and select the desired option from the menu now displaying.



Data (blood glucose, carbohydrates, insulin) in the list

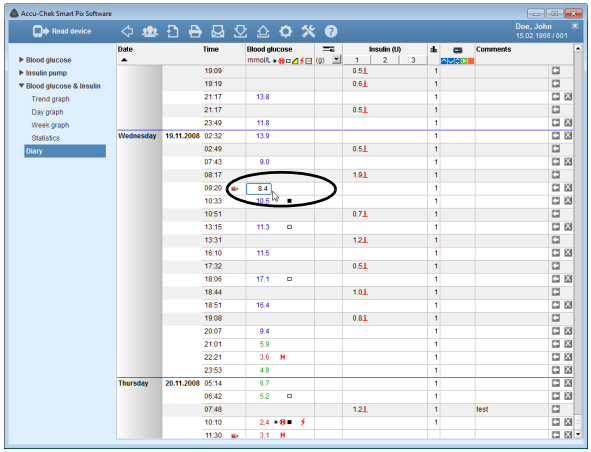
The records in the various columns are displayed with the following units:

- *Blood glucose*
  The unit is the same as the setting on the meter from which the data was read.
- *Carbohydrates*
  You can set the unit yourself. To change the displayed unit, click the button next to it and select the desired unit. The unit selected here will also be used for the report.
- *Insulin*
  The unit is always *U*.

The following limitations apply when entering data:

- In entries read from insulin pumps, you can only enter carbohydrates and comments but no blood glucose or further insulin amounts.
- You cannot change blood glucose data read from devices but mark them with events.
- You can enter blood glucose values only in manually created entries.

Icons used in list entries to provide insulin pump information correspond to the icons described in the insulin pump reports.



Entering and editing blood glucose values

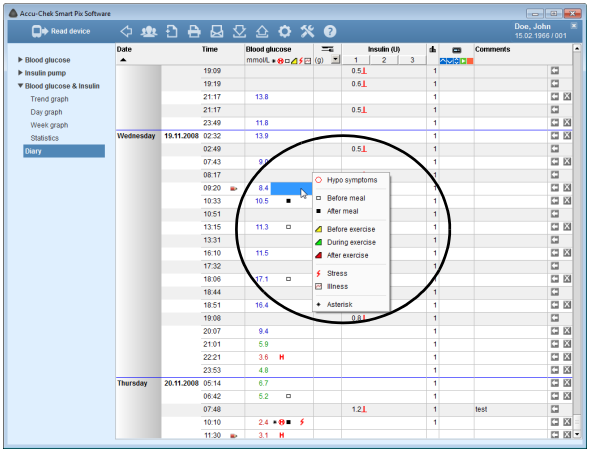
To enter a blood glucose value in a manually created list entry:

- In the desired entry, click the *Blood glucose* column.
- If the input field is highlighted, you can enter the value.
- Complete your data input by pressing the Enter key.

As soon as you have completed your data input, the entry is marked as a manual list entry with the icon.

To change or delete a blood glucose value which has been entered manually:

- Double-click the value you wish to change or delete. The cursor now flashes in that input field.
- Delete or change the value and then press the Enter key.



To mark a blood glucose value with an event:

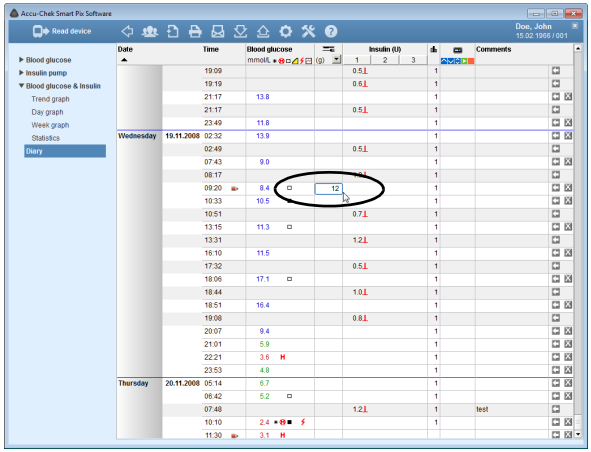
- In the desired entry, click the section to the right of the blood glucose value.
- From the menu now displayed select the desired event by clicking it once.

The event selected is now displayed as an icon to the right of the blood glucose value. You can mark a blood glucose value with up to six events.

To delete an event icon:

- In the desired entry, click the section to the right of the blood glucose value.
- The icons of events already assigned are displayed with a highlighted border in the menu now displayed. Click the highlighted icon once to delete it.

This icon is now removed from this entry.



Entering and editing carbohydrates

To enter a carbohydrate amount in a list entry created manually or read from a meter or insulin pump:

- In the desired entry, click the *Carbohydrates* column.
- If the input field is highlighted, you can enter the value.
- Complete your data input by pressing the Enter key.

To change or delete a carbohydrate amount which has been entered manually:

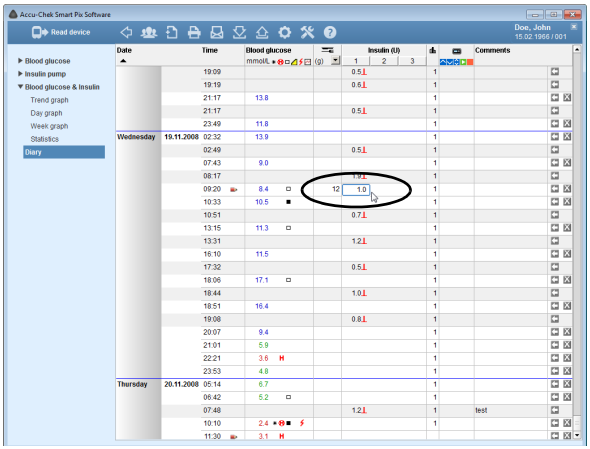
- Double-click the value you wish to change or delete. The cursor now flashes in that input field.
- Delete or change the value and then press the Enter key.

Entering and editing insulin doses

Insulin types 1, 2 and 3 are assigned as follows in the list:

If you use an insulin pump, the pump insulin is automatically entered as *Insulin 1*.

If you do not use an insulin pump, you may, e.g., assign *Insulin 1* to the short-acting insulin you use; assign *Insulin 2* to the long-acting insulin; and assign *Insulin 3* to the pre-mixed insulin.

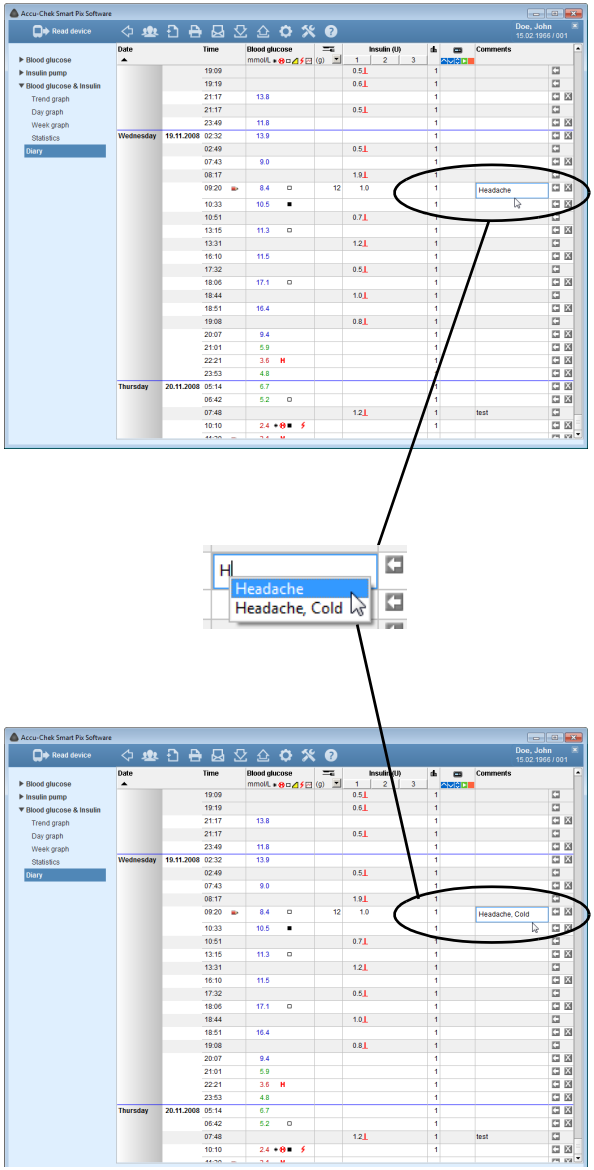


To enter an insulin dose in a list entry created manually or read from a meter:

- In the desired entry, click the *Insulin 1, 2* or *3* column (you may have given these columns different names).
- If the input field is highlighted, you can enter the value.
- Complete your data input by pressing the Enter key.

To change or delete an insulin dose which has been entered manually:

- Double-click the value you wish to change or delete. The cursor now flashes in that input field.
- Delete or change the value and then press the Enter key.



Adding, editing and deleting comments

To add a comment to a list entry:

- In the *Comments* column, click the entry to which you wish to add the comment.
- When the comments field is highlighted, you can enter the desired text. All entered comments will be saved in a list which will appear automatically upon entry of your next comment. The list will display all comments that start with the same initial letter as your new comment. Simply click the comment displayed in the list if you wish to enter it again.
- You can enter up to 30 characters for each comment. Complete your text input by pressing the Enter key.

To change an existing comment:

- Double-click the comment you wish to change. The cursor now flashes in that text field.
- Change the text as you wish.
- Complete your text input by pressing the Enter key.

To delete an existing comment:

- Double-click the comment you wish to delete. The cursor now flashes in that text field.
- Delete the text.
- After deleting the text, press the Enter key.

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6 Appendix

6.1 Disposal

The USB flash drive falls inside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment, WEEE). Do not dispose of it in household waste. Dispose of the USB flash drive in an environmentally sound manner by handing it in to a collection point or to your distributor.

6.2 Cleaning the USB flash drive

Clean the USB flash drive while it is disconnected. Use cloths slightly moistened with cleaning fluid and make sure that no liquid gets inside the device casing.

6.3 Using a USB flash drive

Important note: Do not remove the USB flash drive containing the Accu-Chek Smart Pix software while data is being exchanged. Doing so could cause irreparable damage to files. The USB flash drive itself could be damaged, rendering it unusable. To prevent this please follow these instructions for safe removal of the USB flash drive:

- Look for the “Safely Remove Hardware and Eject Media” icon on the Windows taskbar.
- Double-click the icon.
- In the menu displayed, select the removable media (USB flash drive) to be ejected.
- When the “Safe to remove hardware” message appears, you may unplug the USB flash drive.

6.4 Abbreviations

bG	Blood glucose
SD	Standard deviation
AST	Alternative site testing
TBR	Temporary basal rate
HI	Result above the measuring range (indicated on the meter as HI)
LO	Result below the measuring range (indicated on the meter as LO)
Hypo	Hypoglycaemia
U	Insulin dose in International Units
U/h	Insulin dose delivered per hour (basal rate)
HBGI	High blood glucose index
LBGI	Low blood glucose index

7 Accu-Chek Smart Pix software Terms of Use

Using the Accu-Chek Smart Pix software is subject to the following provisions (“Terms”).

1 Data Protection, Privacy and Data Backup

1.1 Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany (“Roche Diagnostics”) does not have any access to data you generate using the Accu Chek Smart Pix software.

1.2 The data you generate using the Accu-Chek Smart Pix software is generated locally on your computer and only stored to the system that you actively select, e.g. the location on your computer where you store the Accu-Chek Smart Pix software.

1.3 The Accu-Chek Smart Pix software USB flash drive is the original media used to provide the software but it is not a suitable media for storing data you have generated using the Accu-Chek Smart Pix software. Avoid potential data loss (e.g., from damages to or loss of the USB flash drive) and always store all data locally on your computer or on a network server. It is your own responsibility to back up your data.

2 Proprietary Rights

All right, title and interest including, but not limited to, copyright, trademarks and other intellectual property rights in and to the structure, design and labeling of the Accu Chek Smart Pix software are owned by Roche Diagnostics and its licensors. Roche Diagnostics retains all rights not expressly granted herein.

3 Limitation of Liability

3.1 Irrespective of the cause of action, Roche Diagnostics' liability shall be limited to damages caused by Roche Diagnostics, its employees or subcontractors due to willful misconduct, gross negligence or, in case of a violation of an essential obligation, i.e. an obligation that is of crucial relevance to the usability of the Accu-Chek Smart Pix software, simple negligence.

3.2 If Roche Diagnostics is held liable for simple negligence under Section 3.1, Roche Diagnostics' liability shall be limited to those typical damages that were reasonably foreseeable at the time you were provided with the Accu-Chek Smart Pix software or, at the latest at the time of the violation of the relevant obligation.

3.3 Roche Diagnostics' liability for any damages caused by the breach of a specific warranty or for damages to be compensated under the Product Liability Act and for damages due to loss of life, injury or prejudice to health remains unaffected.

4 Miscellaneous

4.1 These Terms shall be governed by the laws of Germany; the application of the UN Convention on Contracts for the International Sale of Goods is excluded.

4.2 For disputes arising from or in connection with these Terms, the courts of Mannheim, Germany have exclusive jurisdiction internationally and locally, if you are a merchant, enterprise or public institution.

4.3 If any individual clause of these Terms is invalid or unenforceable, the remainder of the Terms shall not be affected in any way. Ineffective clauses shall be replaced by the legal regulation.

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